

EXHIBIT D

Bruce Alan Rosenzweig, M.D.

Page 1

IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

-----)	FEBRUARY TERM 2014
IN RE: PELVIC MESH)	
LITIGATION)	
)	
MASTER DOCKET)	NO. 829
-----)	-----
)	
ELLA EBAUGH and)	COURT OF COMMON
MARVIN EBAUGH)	PLEAS
)	
Plaintiffs,)	PHILADELPHIA COUNTY
)	
-vs-)	
)	
ETHICON WOMEN'S HEALTH)	JULY TERM 2013
AND UROLOGY, A DIV. OF)	
ETHICON, INC., ET AL.,)	NO. 00866
)	
Defendants.)	
)	
-----)	

The videotaped de bene esse deposition of
BRUCE ALAN ROSENZWEIG, M.D., called for
examination, taken before CORINNE T. MARUT, C.S.R.
No. 84-1968, Registered Professional Reporter and a
Certified Shorthand Reporter of the State of
Illinois, at the JW Marriott Chicago, 151 West
Adams Street, Chicago, Illinois, on July 14, 2017,
commencing at 9:10 a.m.

Bruce Alan Rosenzweig, M.D.

Page 2	Page 4
<p>1 APPEARANCES: 2 ON BEHALF OF THE PLAINTIFFS: 3 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 4 17 East Main Street, Suite 200 5 Pensacola, Florida 32502 6 850-202-1010 7 BY: DANIEL THORNBURGH, ESQ. 8 dthornburgh@awkolaw.com 9 BRAD BRADFORD, ESQ. 10 bbradford@awkolaw.com 11 12 ON BEHALF OF THE DEFENDANTS: 13 BUTLER SNOW LLP 14 500 Office Center Drive, Suite 400 15 Fort Washington, Pennsylvania 19034 16 267-513-1885 17 BY: NILS B. (BURT) SNELL, ESQ. 18 Burt.Snell@butlersnow.com 19 20 BUTLER SNOW LLP 21 1020 Highland Colony Parkway, Suite 1400 22 Ridgeland, Mississippi 39158 23 601-985-4596 24 BY: PAUL S. ROSENBLATT, ESQ. Paul.Rosenblatt@butlersnow.com</p> <p>ALSO PRESENT:</p> <p>RAQUEL LaPOINTE, Paralegal, Anderson Law Offices; THOMAS BODYZIAK, Trial Technician.</p> <p>VIDEOTAPED BY: MILO SAVICH</p> <p>REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968</p>	<p>1 E X H I B I T S (Continued) 2 3 EXHIBITS PREVIOUSLY MARKED -- FIRST REFERRED TO</p> <p>P0127..... 290 P0274..... 285 P0279..... 176 P0542..... 186 P0619..... 301 P0716..... 191 P0732..... 130 P0784..... 320 P0842..... 200 P0871..... 164 P0933..... 78 P1080..... 74 P1096..... 288 P1100..... 314 P1177..... 151 P1318..... 134 P1352..... 237 P1403..... 259 P1437..... 327 P1452..... 277 P1553..... 61 P1572..... 84 P1801..... 48 P2225..... 337 P2377..... 165</p>
Page 3	Page 5
<p>1 I N D E X 2 BRUCE ALAN ROSENZWEIG, M.D. EXAMINATION 3 BY MR. THORNBURGH..... 12 4 5 6 CONFERENCE CALL WITH JUSTICE GREENSPAN 7 Pages 102 to 112 8 9 E X H I B I T S 10 11 BR-Secur EXHIBIT MARKED FOR ID 12 13 No. 1 "Summary of Opinions" slide 30 14 No. 2 "Materials Reviewed" slide 32 15 16 No. 3 "Testimony Reviewed by 35 17 Dr. Rosenzweig" slide 18 No. 4 "TVT-Secur" slide 39 19 No. 5 Binder of various Plaintiffs' 78 20 Exhibits referred to by 21 deponent 22 (see First Referred to 23 Exhibits below) 24</p>	<p>1 THE VIDEOGRAPHER: We are now on the record. 2 My name is Milo Savich and I am a videographer for 3 Golkow Technologies. 4 Today's date is July 14, 2017 and the 5 time is 9:10 a.m. 6 This video deposition is being held in 7 Chicago, Illinois in the matter of Ella 8 Cederberg-Ebaugh vs. Ethicon, Inc. et al., which is 9 being heard in the Court of Common Pleas of 10 Philadelphia County, Pennsylvania. The case number 11 is 1307-00866. 12 The deponent is Dr. Bruce Rosenzweig. 13 Will counsel please identify themselves 14 for the record. 15 MR. THORNBURGH: Daniel Thornburgh for the 16 Plaintiff. 17 MR. SNELL: Burt Snell for the Defendants 18 Ethicon and Johnson & Johnson. 19 MR. ROSENBLATT: Paul Rosenblatt for the 20 Defendants Johnson & Johnson and Ethicon, Inc. 21 THE VIDEOGRAPHER: The Court Reporter is Corey 22 Marut who will now swear in the witness and we may 23 then proceed. 24 (WHEREUPON, the witness was duly</p>

Bruce Alan Rosenzweig, M.D.

Page 6	Page 8
<p>1 sworn.)</p> <p>2 MR. SNELL: This is counsel for Ethicon and</p> <p>3 Johnson & Johnson. Mr. Thornburgh and I had a</p> <p>4 discussion before the deposition and I advised that</p> <p>5 I had an objection to put on the record, so I'd</p> <p>6 like to do that now.</p> <p>7 I want to put an objection on the record</p> <p>8 to the use of this de bene esse deposition taken in</p> <p>9 the Ebaugh case in Pennsylvania State Court from</p> <p>10 being used in any Federal MDL trials.</p> <p>11 To date, no Plaintiff in the Federal MDL</p> <p>12 has yet attempted to use Dr. Rosenzweig's</p> <p>13 Pennsylvania TVT Carlino deposition in lieu of a</p> <p>14 live trial appearance in Federal Court.</p> <p>15 To the extent that any Plaintiff</p> <p>16 attempts to use in a federal trial the Carlino or</p> <p>17 Ebaugh deposition transcript in lieu of a live</p> <p>18 appearance, Defendants will move to strike and</p> <p>19 quash the use of these depositions.</p> <p>20 Plaintiffs' cross-notice of</p> <p>21 Dr. Rosenzweig's deposition is improper because the</p> <p>22 Ebaugh deposition is a Pennsylvania de bene esse</p> <p>23 deposition for many reasons.</p> <p>24 The Ebaugh deposition of Dr. Rosenzweig</p>	<p>1 in Federal Court subject to the restrictions of the</p> <p>2 Federal Rules, including Rule 32.</p> <p>3 Also in federal practice under</p> <p>4 FRCP 26(b), the scope of a deposition is</p> <p>5 concomitant with the scope of discovery.</p> <p>6 Objections are typically limited to</p> <p>7 those that might be waived if not made at the time</p> <p>8 under Rule 32(d)(3), i.e., objections to the manner</p> <p>9 of taking the deposition, the form of a question or</p> <p>10 answer, the oath or affirmation, a party's conduct</p> <p>11 and other matters that might be immediately</p> <p>12 corrected.</p> <p>13 With the knowledge that it will be a</p> <p>14 de bene esse deposition for Ebaugh, Ethicon's</p> <p>15 attorneys will have different strategic</p> <p>16 considerations for Dr. Rosenzweig's Ebaugh</p> <p>17 deposition than it would in a typical Federal Court</p> <p>18 deposition.</p> <p>19 It's inherently fair -- unfair and</p> <p>20 prejudicial for Ethicon to be forced to compromise</p> <p>21 its strategy for the de bene esse deposition for</p> <p>22 the purposes of a Federal Court discovery</p> <p>23 deposition or vice versa, for example, Ethicon may</p> <p>24 choose to forego certain objections. Ethicon</p>
Page 7	Page 9
<p>1 is a de bene esse deposition, also known as a trial</p> <p>2 deposition. A de bene esse deposition is a</p> <p>3 substitute for live testimony at trial and is</p> <p>4 conducted under the Trial Rules of Evidence rather</p> <p>5 than as a discovery deposition.</p> <p>6 Thus, the Ebaugh deposition will be</p> <p>7 conducted pursuant to the Pennsylvania Trial Rules</p> <p>8 of Evidence, not the Federal Rules for discovery.</p> <p>9 There are significant differences between the</p> <p>10 Pennsylvania Rules of Evidence and procedure which</p> <p>11 will govern the de bene esse deposition in the</p> <p>12 Ebaugh trial case as compared to the Federal Rules,</p> <p>13 and these differences can affect lines of</p> <p>14 questioning, including strategic cross-examination</p> <p>15 decisions.</p> <p>16 There are other significant evidentiary</p> <p>17 differences between Federal Court and Pennsylvania</p> <p>18 with regard to the use of learned treatises and</p> <p>19 expert reliance materials.</p> <p>20 Also, the Fourth Circuit, as noted in</p> <p>21 Tatman v. Collins, the Federal Rules of Civil</p> <p>22 Procedure do not distinguish between depositions</p> <p>23 taken for discovery and depositions taken for</p> <p>24 trial, rather. A deposition may be used at trial</p>	<p>1 should not be forced into this dilemma by</p> <p>2 Plaintiffs' improper cross-notice.</p> <p>3 Additionally and finally,</p> <p>4 Dr. Rosenzweig, the witness, is not unavailable in</p> <p>5 the federal cases. He has testified before in the</p> <p>6 federal trials. He's typically paid, upon my</p> <p>7 information, approximately \$10,000 a day to testify</p> <p>8 at trial and he has testified in numerous MDL cases</p> <p>9 as well as other State Court cases around this</p> <p>10 country for this litigation as well as other</p> <p>11 manufacturers litigation.</p> <p>12 MR. THORNBURGH: Are you done?</p> <p>13 MR. SNELL: Finally, Ethicon should not be</p> <p>14 forced to refrain -- reframe their de bene esse</p> <p>15 deposition to focus on federal Daubert issues as</p> <p>16 opposed to the Frye issues in Pennsylvania.</p> <p>17 In sum, the Ebaugh deposition has</p> <p>18 different -- a different purpose, different issues</p> <p>19 and will be taken under different rules of</p> <p>20 evidence, subject to different pretrial rulings and</p> <p>21 falls under a different expert standard.</p> <p>22 Plaintiffs' improper cross-notice</p> <p>23 seeking to have this deposition apply to all cases</p> <p>24 in the MDL should be rejected.</p>

Bruce Alan Rosenzweig, M.D.

Page 10	Page 12
<p>1 For the reasons just discussed, in the</p> <p>2 event that any Federal MDL Plaintiff attempts to</p> <p>3 use Dr. Rosenzweig's TVT de bene esse deposition</p> <p>4 taken in the Carlino Pennsylvania case or his</p> <p>5 TVT-Secur de bene esse deposition taken in the</p> <p>6 Ebaugh Pennsylvania State Court case in lieu of</p> <p>7 live testimony, Ethicon will move to strike and</p> <p>8 quash the use of the designations.</p> <p>9 And I thank you for your indulgence.</p> <p>10 MR. THORNBURGH: First of all, this is Dan</p> <p>11 Thornburgh for the Plaintiff.</p> <p>12 This is the first time that I'm being</p> <p>13 made aware of an objection, a quite lengthy</p> <p>14 objection, by Defendants being made with respect to</p> <p>15 the current Notice in the Ebaugh matter as well as</p> <p>16 the cross-notice that was filed several weeks ago.</p> <p>17 So, we obviously haven't had an</p> <p>18 opportunity to read the brief or motion that was</p> <p>19 just read into the record at length for the first</p> <p>20 time, just for the very first time right before</p> <p>21 this deposition is about to begin.</p> <p>22 So, our position is that we can handle</p> <p>23 this objection later, but we also should be able to</p> <p>24 handle quite efficiently the issues that were</p>	<p>1 MR. SNELL: No. Thank you very much.</p> <p>2 BRUCE ALAN ROSENZWEIG, M.D.,</p> <p>3 called as a witness herein, having been first duly</p> <p>4 sworn, was examined and testified as follows:</p> <p>5 DIRECT EXAMINATION</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Good morning, Dr. Rosenzweig.</p> <p>8 A. Good morning.</p> <p>9 Q. How are you doing?</p> <p>10 A. Fine, thank you.</p> <p>11 Q. Good. Would you please briefly -- would</p> <p>12 you please state your name to the ladies and</p> <p>13 gentlemen of the jury.</p> <p>14 A. Bruce Alan Rosenzweig.</p> <p>15 Q. Now, Dr. Rosenzweig, you've already</p> <p>16 provided trial testimony concerning the TVT-R and</p> <p>17 TVT-O devices, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And those have been preserved, to the</p> <p>20 best of your understanding, by video?</p> <p>21 A. Yes.</p> <p>22 Q. And as defense counsel alluded to before</p> <p>23 we -- on the record, we have an agreement that we</p> <p>24 will not, at least in the Ebaugh case, but I think</p>
Page 11	Page 13
<p>1 addressed by cross-counsel by editing video and</p> <p>2 cutting video so that it complies with either the</p> <p>3 Federal Rules or with the Pennsylvania State Rules.</p> <p>4 And that's it.</p> <p>5 MR. SNELL: I'll just reply that these issues</p> <p>6 were initially raised before the Carlino TVT trial</p> <p>7 deposition of Dr. Rosenzweig by the defense where</p> <p>8 there it was noticed by Plaintiffs to be a TVT,</p> <p>9 TVT-O and TVT-Secur deposition and these issues</p> <p>10 were raised and objections were filed and as I</p> <p>11 understand the judge held a hearing and did not</p> <p>12 reach all those issues.</p> <p>13 The judge's ruling at the hearing was to</p> <p>14 the parties to just go forward at that time and</p> <p>15 proceed and do Dr. Rosenzweig's de bene esse TVT</p> <p>16 Carlino deposition, which we accomplished in</p> <p>17 December 2015 and January 2016 as I recall.</p> <p>18 MR. THORNBURGH: And I appreciate that</p> <p>19 position, but obviously there was no formal</p> <p>20 objection filed with respect to the Notice of</p> <p>21 Deposition and Cross-Notice of Deposition for which</p> <p>22 brings us here today for the deposition,</p> <p>23 preservation deposition of Dr. Rosenzweig.</p> <p>24 Anything further, counsel?</p>	<p>1 that agreement should extend beyond that, to not</p> <p>2 cover old ground or cover your trial testimony that</p> <p>3 you've provided in the prior preservation</p> <p>4 videotaped depositions in Carlino and so forth.</p> <p>5 MR. SNELL: Since you do raise that, I will</p> <p>6 make a statement with regards to --</p> <p>7 MR. THORNBURGH: You did already.</p> <p>8 MR. SNELL: With regard to the TVT-O. I think</p> <p>9 you threw in TVT-O. And it's my position as I've</p> <p>10 indicated to Plaintiffs' counsel that I do not</p> <p>11 believe the TVT-O deposition in the Ramirez Texas</p> <p>12 case, State Court case, was a part of that</p> <p>13 continuation.</p> <p>14 But counsel and I have agreed that for</p> <p>15 Pennsylvania, and my position is for Pennsylvania</p> <p>16 obviously only, for the Pennsylvania mass tort</p> <p>17 program that we both agree we don't have to recover</p> <p>18 issues covered in Carlino and that both sides can</p> <p>19 designate testimony from the Carlino TVT deposition</p> <p>20 and each side maintains its objections, and that's</p> <p>21 my position to your position.</p> <p>22 MR. THORNBURGH: We obviously have a different</p> <p>23 position. We believe that Ramirez and Carlino</p> <p>24 preservation depositions can be used as preservation</p>

Bruce Alan Rosenzweig, M.D.

Page 14	Page 16
<p>1 depos, depositions for the purposes of cutting 2 video for either Ebaugh or other cases. 3 MR. SNELL: Okay. I understand your position. 4 I just want to make sure mine was clear so that we 5 understood. 6 And I don't plan to be duplicative, but 7 there are some things that I will have to get into 8 that have been covered in Carlino because of the 9 nature of this and I'm sure your examination. 10 BY MR. THORNBURGH: 11 Q. The point is, Doctor, you've already 12 provided preservation testimony in the Ramirez and 13 Carlino matters, correct? 14 A. Correct. 15 Q. And we -- I will attempt not to cover 16 the issues or testimony that you've already 17 provided in those other cases? 18 A. Thank you. 19 MR. THORNBURGH: And, counsel, because no 20 formal objection was made with respect to these two 21 Notices in this case, the Notice in Ebaugh for the 22 deposition and the Cross-Notice in the MDL, I've 23 prepared under the assumption that we would be able 24 to use some of the testimony from those prior</p>	<p>1 side can designate from the TVT Carlino 2 de bene esse deposition, so we don't have to redo 3 everything previously covered with him in this 4 TVT-Secur de bene esse deposition, is okay. And I 5 said both parties preserve their objections. Okay? 6 And I didn't hear back from 7 Mrs. Baldwin. And I did copy you. So I appreciate 8 that. That last e-mail was July 12, 7:52 p.m. 9 MR. THORNBURGH: Which my interpretation of 10 that is that you weren't objecting. But anyway. 11 We can take that up later on. 12 BY MR. THORNBURGH: 13 Q. So, Dr. Rosenzweig, you've already 14 provided prior testimony, and I will not attempt to 15 ask you questions that you've already been asked at 16 those prior depositions. Okay? 17 A. Thank you. 18 Q. But we are here regarding the TVT-Secur, 19 is that correct? 20 A. Correct. 21 Q. And are you prepared to offer your 22 expert opinions concerning the TVT-Secur device? 23 A. Correct. 24 Q. How did you become familiar -- strike</p>
Page 15	Page 17
<p>1 preservation cases. 2 MR. SNELL: Okay. And I understand that. And 3 as you know, just so the record is clear, I did 4 e-mail you and Ms. Baldwin who is Pennsylvania 5 counsel about this issue and I raised that with 6 regard to the TVT-O, that was a Ramirez Texas State 7 Court case and did not fall under this agreement. 8 But I did also say I am fine with both 9 sides agreeing and being able to designate from the 10 TVT Carlino deposition in Pennsylvania for this 11 case. 12 MR. THORNBURGH: I didn't see any e-mail from 13 you. I'm not saying you didn't. You don't have to 14 go find it. 15 MR. SNELL: Okay. 16 MR. THORNBURGH: I didn't see any e-mail from 17 you that explicitly argued or held the position 18 that the Ramirez preservation deposition would not 19 be -- that we would not be -- or that you were 20 objecting to the use of that at other trials. 21 MR. SNELL: Okay. Well, July 12, 2017, 2:15 22 p.m. is when I sent that e-mail and then my 23 follow-up to it where I stated I am okay with 24 agreeing that in the Pennsylvania cases that either</p>	<p>1 that. 2 Are you familiar with the TVT-Secur 3 system? 4 A. Yes. 5 Q. And how did you first become familiar 6 with the TVT-Secur system? 7 MR. SNELL: Can I interrupt you and ask you 8 one question just for clarity. So, are you relying 9 on his qualifications back in TVT Carlino -- 10 MR. THORNBURGH: Yeah. I am. 11 MR. SNELL: -- for the basis of this? 12 MR. THORNBURGH: I am. 13 MR. SNELL: For this. 14 MR. THORNBURGH: I am. Do you have an 15 objection to relying -- 16 MR. SNELL: Yes. 17 MR. THORNBURGH: -- on his testimony about his 18 qualifications? 19 MR. SNELL: No, I don't have any -- I don't 20 have any objection to you relying on those 21 qualifications. 22 MR. THORNBURGH: Are you going to have an 23 objection -- 24 MR. SNELL: We very well may have an objection</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 18</p> <p>1 at trial.</p> <p>2 MR. THORNBURGH: Here's the problem. Here's</p> <p>3 where I am prejudiced because I have prepared to</p> <p>4 ask questions today and rely on the testimony</p> <p>5 concerning his qualifications --</p> <p>6 MR. SNELL: I'm fine with that.</p> <p>7 MR. THORNBURGH: -- so we don't have to cover</p> <p>8 the same background, training and experience he's</p> <p>9 already testified to in other cases.</p> <p>10 MR. SNELL: And I'm okay with that. I just</p> <p>11 want to understand and make sure that that's what</p> <p>12 you were doing because you kind of jumped into</p> <p>13 substantive things.</p> <p>14 MR. THORNBURGH: That's the next thing I was</p> <p>15 going to say, so we won't cover your background,</p> <p>16 knowledge and training.</p> <p>17 MR. SNELL: As you know, in Pennsylvania you</p> <p>18 actually have to formally take the step and qualify</p> <p>19 an expert before.</p> <p>20 MR. THORNBURGH: I understand that. But we</p> <p>21 are not going on -- we are relying on the testimony</p> <p>22 he's provided --</p> <p>23 MR. SNELL: Got you.</p> <p>24 MR. THORNBURGH: -- concerning his knowledge,</p>	<p style="text-align: right;">Page 20</p> <p>1 properly before us within even Pennsylvania.</p> <p>2 But I just want to understand if you</p> <p>3 were going to -- if you weren't going to do</p> <p>4 anything on qualifications and you were going to go</p> <p>5 right to substance. That's all I was trying to</p> <p>6 understand.</p> <p>7 MR. THORNBURGH: I'm going to try to jump</p> <p>8 mostly into substance. I am going to talk a little</p> <p>9 bit about his qualifications with Secur with an</p> <p>10 understanding that we can at least use the Carlino</p> <p>11 testimony concerning his background and</p> <p>12 qualifications.</p> <p>13 MR. SNELL: Yes. And I am totally fine with</p> <p>14 that.</p> <p>15 MR. THORNBURGH: Okay. Hopefully we won't</p> <p>16 have interruptions and objections throughout the</p> <p>17 rest of this de bene esse deposition because it's</p> <p>18 going to take us a week to finish.</p> <p>19 MR. SNELL: I didn't mean to. I mean, it's</p> <p>20 because of the unique way that Pennsylvania does it</p> <p>21 versus MDL and because I thought you were just</p> <p>22 jumping, that's the only reason I wanted to make</p> <p>23 sure I understood.</p> <p>24 As I said, your qualifications, I</p>
<p style="text-align: right;">Page 19</p> <p>1 training and experience in the prior cases.</p> <p>2 Now, we will also talk about his</p> <p>3 qualifications today to talk about the TVT-Secur</p> <p>4 device.</p> <p>5 So, it's sort of two steps, right. He's</p> <p>6 given a background, training -- he's testified</p> <p>7 about his background, training and experience and</p> <p>8 qualifications in prior preservation depositions.</p> <p>9 Right?</p> <p>10 MR. SNELL: Yes.</p> <p>11 MR. THORNBURGH: On the TVT-O and</p> <p>12 TVT Retropubic devices. This is a TVT-R, so I'm</p> <p>13 going to briefly talk about his experience with the</p> <p>14 TVT-Secur.</p> <p>15 MR. SNELL: Okay. Okay.</p> <p>16 MR. THORNBURGH: But I understand that you're</p> <p>17 going to object later on to us playing video from</p> <p>18 the -- either the Carlino or Ramirez cases with</p> <p>19 respect to his testimony about his qualifications?</p> <p>20 MR. SNELL: No.</p> <p>21 MR. THORNBURGH: Okay.</p> <p>22 MR. SNELL: I don't have a problem with</p> <p>23 Carlino, as I've stated, right. I do have a</p> <p>24 problem with Ramirez. Ramirez I don't believe is</p>	<p style="text-align: right;">Page 21</p> <p>1 understand you are using that from Carlino. I</p> <p>2 don't have a problem with that. If we have</p> <p>3 objections to that part, they will be objections</p> <p>4 that we've always had just like you would have</p> <p>5 objections to our qualifications cross of him if</p> <p>6 you had it.</p> <p>7 MR. THORNBURGH: Right.</p> <p>8 MR. SNELL: That's the reason I butted in.</p> <p>9 I'm sorry.</p> <p>10 MR. THORNBURGH: Just to make one quick</p> <p>11 statement. It's our position that we can use</p> <p>12 Carlino and Ramirez. You said Carlino, but we will</p> <p>13 handle that -- we will take that up later on.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. All right, Doctor. How did you first</p> <p>16 become familiar with the TVT-Secur system?</p> <p>17 A. I was first introduced to the TVT-Secur</p> <p>18 by Ethicon sales representatives. They showed me</p> <p>19 promotional material and that's how I first became</p> <p>20 introduced to the TVT-Secur.</p> <p>21 Q. And when approximately did you first</p> <p>22 become introduced and familiar with the TVT-Secur</p> <p>23 system?</p> <p>24 A. If I recall, it was probably late 2006,</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 22</p> <p>1 but it might have been early 2007.</p> <p>2 Q. Okay. And you've testified previously</p> <p>3 about the TVT Retropubic and the TVT-Obturator</p> <p>4 devices. But the TVT-Secur system, can you briefly</p> <p>5 explain what it is and what it is intended to</p> <p>6 treat?</p> <p>7 A. The TVT-Secur system is a device that is</p> <p>8 used to treat stress urinary incontinence. I've</p> <p>9 already described for the jury stress urinary</p> <p>10 incontinence and the concept of a midurethral sling</p> <p>11 used for stress urinary incontinence.</p> <p>12 The TVT-Secur device is what's known as</p> <p>13 a single-incision sling meaning that there's a</p> <p>14 vaginal incision and there are no exit points as I</p> <p>15 described for the other what's called full-length</p> <p>16 sling. So, this is a shorter sling.</p> <p>17 It's still made out of the same</p> <p>18 polypropylene. It still has the same</p> <p>19 characteristics that I've described as being</p> <p>20 heavy-weight, small-pore polypropylene. It is used</p> <p>21 to treat the same condition which is stress urinary</p> <p>22 incontinence and it's placed in the same position,</p> <p>23 which is the midurethra.</p> <p>24 However, those are where the</p>	<p style="text-align: right;">Page 24</p> <p>1 into any of your patients?</p> <p>2 A. I have not used the TVT-Secur device on</p> <p>3 one of my patients.</p> <p>4 Q. And why is that?</p> <p>5 A. When I was first introduced to it,</p> <p>6 frankly, I didn't think it would work.</p> <p>7 Q. And is that after you had an opportunity</p> <p>8 to speak with the sales representatives and look at</p> <p>9 the actual physical device?</p> <p>10 MR. SNELL: Object; leading.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. What led you to that conclusion, Doctor?</p> <p>13 A. Not only looking at the promotional</p> <p>14 material but also looking at the device.</p> <p>15 Q. And as part of your treatment of</p> <p>16 patients, did you ever treat any patients who</p> <p>17 experienced complications as a result of the</p> <p>18 TVT-Secur device?</p> <p>19 A. Yes, I have. I've previously described</p> <p>20 for the jury my experience in treating</p> <p>21 complications of midurethral slings and that</p> <p>22 includes also treating complications of the</p> <p>23 TVT-Secur device.</p> <p>24 MR. SNELL: Object. Non-responsive.</p>
<p style="text-align: right;">Page 23</p> <p>1 similarities between what I have described before</p> <p>2 as the full-length midurethral sling such as the</p> <p>3 TVT and the TVT-Obturator is that it is a</p> <p>4 heavier -- excuse me -- a stiffer, shorter sling</p> <p>5 that had never been used before.</p> <p>6 The length is 8 centimeters. That</p> <p>7 length had never been used before in a midurethral</p> <p>8 sling.</p> <p>9 It was cut by a laser. I've already</p> <p>10 given testimony about the difference between</p> <p>11 mechanical-cut and laser-cut. And that had never</p> <p>12 been used before.</p> <p>13 It has an arrowhead introducer to get</p> <p>14 the short, rigid mesh into the position to act as</p> <p>15 part of the midurethra. That had never been used</p> <p>16 before.</p> <p>17 And the ends of the short, rigid mesh</p> <p>18 have a dissolvable fleece tip. That had never been</p> <p>19 used before.</p> <p>20 Q. And we're going to get into more</p> <p>21 specifics of those design characteristics</p> <p>22 throughout the day. But did you ever -- can you</p> <p>23 tell the ladies and gentlemen of the jury whether</p> <p>24 or not you've ever implanted a TVT-Secur device</p>	<p style="text-align: right;">Page 25</p> <p>1 BY MR. THORNBURGH:</p> <p>2 Q. And with respect to those complications,</p> <p>3 could you briefly -- I know you've testified about</p> <p>4 complications associated with these -- with the</p> <p>5 full-length midurethral slings like the</p> <p>6 TVT Retropubic and TVT-Obturator, but how are those</p> <p>7 complications impacted, if at all, by the TVT-Secur</p> <p>8 device?</p> <p>9 A. I've treated complications associated</p> <p>10 with the TVT-Secur device both surgically by</p> <p>11 removing either a portion of the device when they</p> <p>12 cause complications or the majority of the device.</p> <p>13 I also treat complications without</p> <p>14 surgery using modalities such as therapies inside</p> <p>15 the vagina to treat pain, pain with intercourse,</p> <p>16 also doing blocking nerves that can treat the pain</p> <p>17 associated with the midurethral slings including</p> <p>18 the Secur and pain with intercourse.</p> <p>19 I've also treated patients with things</p> <p>20 like biofeedback, electrical stimulation, physical</p> <p>21 therapy for problems with voiding dysfunction</p> <p>22 meaning that they can't empty their bladder</p> <p>23 completely or from entities such as overactive</p> <p>24 bladders, which the patient has an irritation of</p>

7 (Pages 22 to 25)

Bruce Alan Rosenzweig, M.D.

Page 26	Page 28
<p>1 their bladder which makes them need to void</p> <p>2 frequently, urgently or get up at night to void.</p> <p>3 Q. Now, as part of your treatment of</p> <p>4 patients who were experiencing complications from a</p> <p>5 Secur device, TVT-Secur device, did you have to</p> <p>6 become familiar with the TVT-Secur system?</p> <p>7 A. Yes.</p> <p>8 Q. And what did you do to become familiar</p> <p>9 with the TVT-Secur system?</p> <p>10 A. I looked at again the promotional</p> <p>11 brochures. I reviewed the Instructions for Use,</p> <p>12 which is a pamphlet that comes with each device. I</p> <p>13 discussed this with colleagues of mine.</p> <p>14 Also, I have looked at internal Ethicon</p> <p>15 documents, internal -- or deposition testimony from</p> <p>16 key Ethicon employees, both scientists and Medical</p> <p>17 Directors, and a review of the scientific</p> <p>18 literature.</p> <p>19 Q. Did you have an opportunity to see if</p> <p>20 the IFU or the Information for Use for the Secur</p> <p>21 device -- strike that.</p> <p>22 In your private practice did you have an</p> <p>23 opportunity, I think you've testified to this</p> <p>24 already, but did you have an opportunity to review</p>	<p>1 IFU?</p> <p>2 A. Yes.</p> <p>3 Q. And was your review of the Information</p> <p>4 for Use for the TVT-Secur helpful to you in</p> <p>5 treating the complications that your patients were</p> <p>6 experiencing?</p> <p>7 A. Well, the Instructions for Use, again,</p> <p>8 gives information about how to use the device, how</p> <p>9 to implant the device. But it does not contain</p> <p>10 information on how to treat complications or how to</p> <p>11 remove the device.</p> <p>12 Q. And have you been qualified as an expert</p> <p>13 witness in any federal courts in the United States?</p> <p>14 A. Yes.</p> <p>15 Q. And have you been -- where have you been</p> <p>16 qualified, if you can recall?</p> <p>17 A. In West Virginia and North Carolina.</p> <p>18 Q. And have you been qualified as an expert</p> <p>19 to offer opinions on the same topics that we're</p> <p>20 speaking about here today in any State Court in the</p> <p>21 United States?</p> <p>22 A. Yes.</p> <p>23 Q. And what courts specifically?</p> <p>24 A. In California, Missouri, Texas and here</p>
Page 27	Page 29
<p>1 the Information for Use related to the TVT-Secur</p> <p>2 device?</p> <p>3 MR. SNELL: Object; leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Because I got an objection, let me ask</p> <p>8 again.</p> <p>9 What is a -- the IFU?</p> <p>10 A. The IFU is what's called the</p> <p>11 Instructions for Use. It is a pamphlet that comes</p> <p>12 with the medical device, the TVT-Secur.</p> <p>13 It contains the indications to use --</p> <p>14 for the use of the device, which is the treatment</p> <p>15 of stress urinary incontinence, which I've</p> <p>16 previously described for the jury; the</p> <p>17 contraindications, which are the women that you</p> <p>18 should not use the device on; how to implant the</p> <p>19 device, to use the device; what are the adverse</p> <p>20 reactions; what are the risks associated with the</p> <p>21 device; and what is the description of the device.</p> <p>22 Q. Okay. And when you are treating your</p> <p>23 patients who had complications from the TVT-Secur</p> <p>24 device, did you have an opportunity to review the</p>	<p>1 in Philadelphia.</p> <p>2 Q. And have you been qualified as an expert</p> <p>3 witness to offer expert opinion testimony with</p> <p>4 respect to the TVT-Secur device specifically?</p> <p>5 A. Yes.</p> <p>6 Q. In what courts?</p> <p>7 A. In Philadelphia.</p> <p>8 Q. Now, Doctor, in the course of the</p> <p>9 testimony that you'll be providing today, do you</p> <p>10 understand that if you offer an opinion that it</p> <p>11 must be to a reasonable degree of medical</p> <p>12 certainty?</p> <p>13 A. Yes.</p> <p>14 Q. And so that I don't have to keep</p> <p>15 repeating myself over and over throughout the day,</p> <p>16 can we have an agreement that if you offer any</p> <p>17 opinion that you will offer it to a reasonable</p> <p>18 degree of medical certainty?</p> <p>19 A. Yes.</p> <p>20 Q. And if you have any opinions that are</p> <p>21 not to a reasonable degree of medical certainty,</p> <p>22 will you let us know?</p> <p>23 A. Yes.</p> <p>24 Q. We are going to spend most of the day</p>

8 (Pages 26 to 29)

Bruce Alan Rosenzweig, M.D.

Page 30	Page 32
<p>1 discussing many of the materials that you reviewed</p> <p>2 in this case. But before we do that, can you tell</p> <p>3 the jury whether or not you came to any conclusions</p> <p>4 or opinions about the TVT-Secur device?</p> <p>5 A. Yes, I did.</p> <p>6 Q. And did you prepare a slide summarizing,</p> <p>7 briefly summarizing, those opinions that will help</p> <p>8 you explain those opinions to the jury?</p> <p>9 A. Yes, I did.</p> <p>10 MR. THORNBURGH: Tom, can we go ahead and show</p> <p>11 Slide No. 1.</p> <p>12 MR. SNELL: Do you have a copy, counsel?</p> <p>13 MR. THORNBURGH: Yes, I do.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. I will go ahead and mark as I think we</p> <p>16 will call it R -- I'm sorry -- BR-Secur 1, which is</p> <p>17 the summary of your opinions in this slide.</p> <p>18 (WHEREUPON, a certain document was</p> <p>19 marked as BR-Secur Exhibit No. 1:</p> <p>20 Summary of Opinions slide.)</p> <p>21 MR. SNELL: Are you intending at trial to put</p> <p>22 this up as basically as it looks or bullet points</p> <p>23 as we go along?</p> <p>24 MR. THORNBURGH: We intend to do it a number</p>	<p>1 The Defendants defectively designed the</p> <p>2 TVT-Secur system.</p> <p>3 Q. Now, in -- can you explain to the ladies</p> <p>4 and gentlemen -- strike that.</p> <p>5 Can you explain to the ladies and</p> <p>6 gentlemen of the jury what you were asked to do in</p> <p>7 this case?</p> <p>8 A. I was asked to review materials and</p> <p>9 deposition testimony, the literature, to review the</p> <p>10 design, the development and the testing of the</p> <p>11 TVT-Secur device.</p> <p>12 Q. And did you prepare a slide that would</p> <p>13 assist you in explaining to the jury the materials</p> <p>14 that you reviewed and relied upon in offering your</p> <p>15 opinions?</p> <p>16 A. Yes.</p> <p>17 Q. Let's go ahead and mark as Exhibit --</p> <p>18 and we'll call it BR-Secur 2. But this is the</p> <p>19 slide that you prepared.</p> <p>20 (WHEREUPON, a certain document was</p> <p>21 marked as BR-Secur Exhibit No. 2:</p> <p>22 Materials Reviewed slide.)</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. And what materials did you review in</p>
Page 31	Page 33
<p>1 of ways, but at this point in the video we would</p> <p>2 put this slide up as it is.</p> <p>3 MR. SNELL: Okay.</p> <p>4 MR. THORNBURGH: This exhibit up as it is.</p> <p>5 MR. SNELL: So I object to that, failing Rule</p> <p>6 705 under Pennsylvania. Go ahead.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And can you provide the ladies and</p> <p>9 gentlemen of the jury with a brief summary of the</p> <p>10 opinions that will be expressed throughout today.</p> <p>11 A. Yes. The Defendants -- excuse me.</p> <p>12 The Defendants failed to adequately test</p> <p>13 the TVT-Secur device.</p> <p>14 The Defendants failed to provide proper</p> <p>15 training to physicians on the TVT-Secur device.</p> <p>16 The Defendants failed to provide proper</p> <p>17 instructions to physicians.</p> <p>18 The Defendants failed to provide</p> <p>19 adequate warnings to physicians.</p> <p>20 The TVT-Secur device is not effective.</p> <p>21 The TVT-Secur device is unreasonably</p> <p>22 dangerous.</p> <p>23 The TVT-Secur device's risks outweigh</p> <p>24 its benefits.</p>	<p>1 preparation for this case and offering the opinions</p> <p>2 that you have related to the TVT-Secur device?</p> <p>3 MR. SNELL: Quick objection to the slide,</p> <p>4 violates Rule 705 facts and bases under</p> <p>5 Pennsylvania law.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I reviewed the medical literature from</p> <p>8 various sources, including PubMed.</p> <p>9 I reviewed Ethicon and J&J internal</p> <p>10 documents, videos, training videos and surgical</p> <p>11 videos.</p> <p>12 I reviewed Ethicon and Johnson & Johnson</p> <p>13 labeling and marketing documents like the</p> <p>14 Instructions for Use.</p> <p>15 I reviewed a significant number of</p> <p>16 depositions of Ethicon and Johnson & Johnson</p> <p>17 current and former employees including scientists</p> <p>18 and Medical Directors.</p> <p>19 I reviewed depositions of Ethicon's</p> <p>20 experts retained in this -- in these matters.</p> <p>21 Q. Okay. And are we going to discuss your</p> <p>22 opinions today and the materials that you reviewed</p> <p>23 and relied upon in coming to your expert</p> <p>24 conclusions?</p>

Bruce Alan Rosenzweig, M.D.

Page 34	Page 36
<p>1 A. Yes.</p> <p>2 Q. And will our discussion include your</p> <p>3 opinions and the support for those opinions from --</p> <p>4 that are derived from the medical publications?</p> <p>5 A. Yes.</p> <p>6 Q. And will we discuss today the opinions</p> <p>7 that you have related to the TVT-Secur device and</p> <p>8 the basis for those opinions and support for those</p> <p>9 opinions that are derived from the internal Ethicon</p> <p>10 company documents?</p> <p>11 A. Yes.</p> <p>12 Q. And will you offer opinions today</p> <p>13 concerning the TVT-Secur device that are supported</p> <p>14 by the depositions of Ethicon and Johnson & Johnson</p> <p>15 current and former employees?</p> <p>16 A. Yes.</p> <p>17 MR. SNELL: Object; leading. Go ahead.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And with respect to the testimony</p> <p>20 reviewed by you, did you provide a slide or create</p> <p>21 a slide that would assist the jury in understanding</p> <p>22 the number of depositions or at least the witnesses</p> <p>23 for whom you've read and reviewed and rely upon</p> <p>24 their testimony?</p>	<p>1 pages of witness testimony you've reviewed in</p> <p>2 rendering your opinions in this case?</p> <p>3 A. Thousands.</p> <p>4 Q. Now, let me ask you this question,</p> <p>5 Doctor: Were -- prior to your involvement in this</p> <p>6 litigation had you ever had an opportunity to</p> <p>7 review Ethicon's internal company documents?</p> <p>8 MR. SNELL: Objection; form. This is a --</p> <p>9 this is a backwards way of going at the</p> <p>10 confidentiality agreement that the parties entered</p> <p>11 into with regard to the designation of company</p> <p>12 documents as confidential.</p> <p>13 MR. THORNBURGH: No, it's not.</p> <p>14 MR. SNELL: That's my position.</p> <p>15 MR. THORNBURGH: It's not.</p> <p>16 MR. SNELL: That's my position. Go ahead.</p> <p>17 MR. THORNBURGH: So, let me ask the question</p> <p>18 again. I understand the objection, so we don't</p> <p>19 interrupt again.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Now, before you were retained as an</p> <p>22 expert witness in this case, did Ethicon and</p> <p>23 Johnson & Johnson make available to you their</p> <p>24 internal company documents?</p>
Page 35	Page 37
<p>1 A. Yes.</p> <p>2 MR. THORNBURGH: I will go ahead and mark as</p> <p>3 BR-Secur 3 a slide presentation.</p> <p>4 (WHEREUPON, a certain document was</p> <p>5 marked as BR-Secur Exhibit No. 3:</p> <p>6 Testimony Reviewed by Dr.</p> <p>7 Rosenzweig slide.)</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Is this the PowerPoint slide that you</p> <p>10 helped create?</p> <p>11 A. Yes.</p> <p>12 Q. And does this provide a list of the</p> <p>13 witnesses for whom you've reviewed their deposition</p> <p>14 testimony and relied upon their -- at least in</p> <p>15 part, for rendering your opinions in this case?</p> <p>16 A. Yes.</p> <p>17 Q. And do you have an estimate, Doctor, of</p> <p>18 how many of those -- the Ethicon internal documents</p> <p>19 that you've reviewed -- strike that.</p> <p>20 Do you have an estimate of how many</p> <p>21 pages of Ethicon documents you reviewed in this</p> <p>22 litigation?</p> <p>23 A. Tens of thousands.</p> <p>24 Q. And do you have an estimate of how many</p>	<p>1 MR. SNELL: Same objection. Go ahead.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. In your practice as a treating physician</p> <p>6 did you ever have access to Ethicon or</p> <p>7 Johnson & Johnson's internal company documents?</p> <p>8 A. No.</p> <p>9 MR. SNELL: Object; relevance. Go ahead.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Why is that?</p> <p>14 A. They're not available to me.</p> <p>15 Q. Now, what types of literature have</p> <p>16 you -- strike that.</p> <p>17 Does Ethicon make available -- does</p> <p>18 Ethicon make their internal company documents</p> <p>19 publicly available to treating physicians,</p> <p>20 urogynecologists, gynecologists such as yourself?</p> <p>21 MR. SNELL: Objection; outside the scope of</p> <p>22 his expert report. Also objection insofar as it is</p> <p>23 not a proper expert basis under Pennsylvania law.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 38</p> <p>1 A. No.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And what types of literature have you</p> <p>4 reviewed in forming your opinions in this case,</p> <p>5 Doctor?</p> <p>6 A. As I've described earlier in prior</p> <p>7 testimony, I've reviewed the lion's share of the</p> <p>8 literature on midurethral slings in general and</p> <p>9 also the TVT-Secur.</p> <p>10 Q. Did you use the same methods in this</p> <p>11 case in reaching your expert conclusions as you use</p> <p>12 in your private practice?</p> <p>13 A. Yes.</p> <p>14 Q. Are you familiar with how the TVT-Secur</p> <p>15 device is designed and how it's supposed to be</p> <p>16 placed in the human body?</p> <p>17 A. Yes.</p> <p>18 Q. And did you help prepare a slide that</p> <p>19 illustrates the TVT-Secur device implant locations?</p> <p>20 A. Yes.</p> <p>21 Q. And would that assist, help you -- help</p> <p>22 you assist the jury in understanding more about the</p> <p>23 TVT-Secur procedure?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 40</p> <p>1 TVT Retropubic device come to market?</p> <p>2 A. Either the end of 1997 or very early in</p> <p>3 1998. The TVT-O came to market in early 2004.</p> <p>4 TVT-Secur was launched towards the end of</p> <p>5 September of 2006, if I recall correctly was</p> <p>6 September 20, 2006.</p> <p>7 Q. Thank you, Doctor.</p> <p>8 Now, Doctor, would it assist you in</p> <p>9 describing the procedure and the device to actually</p> <p>10 have the device and show it to the jury?</p> <p>11 A. Yes.</p> <p>12 Q. Okay.</p> <p>13 MR. THORNBURGH: Can we go off the record</p> <p>14 really quick.</p> <p>15 THE VIDEOGRAPHER: The time is 9:52 a.m. and</p> <p>16 we are going off the video record.</p> <p>17 (WHEREUPON, discussion was had off</p> <p>18 the record.)</p> <p>19 THE VIDEOGRAPHER: The time is 9:52 a.m. and</p> <p>20 we're back on the video record.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Doctor, I'm going to hand you the</p> <p>23 TVT-Secur device in the box that it was sold in.</p> <p>24 A. Thank you.</p>
<p style="text-align: right;">Page 39</p> <p>1 MR. THORNBURGH: I will go ahead and mark as</p> <p>2 BR-Secur 4 the slide entitled "TVT-Secur."</p> <p>3 (WHEREUPON, a certain document was</p> <p>4 marked as BR-Secur Exhibit No. 4:</p> <p>5 "TVT-Secur" slide.)</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Do you recognize this document?</p> <p>8 A. Yes.</p> <p>9 Q. Is this the slide that you created?</p> <p>10 A. I did not create the graphics, but I put</p> <p>11 it together as a slide.</p> <p>12 Q. Okay. And what is the jury seeing in</p> <p>13 this screen, Doctor?</p> <p>14 A. Well, the TVT-Secur can be placed in two</p> <p>15 different fashions, one to resemble the</p> <p>16 TVT Retropubic that I've described earlier, which</p> <p>17 is called the U position, and the other -- the same</p> <p>18 device can be placed in a different fashion so it</p> <p>19 more resembles the TVT-Obturator, which is called</p> <p>20 the hammock position.</p> <p>21 Q. Now, Doctor, you've testified about the</p> <p>22 dates of launch of the first and second generation</p> <p>23 TVT devices, the TVT Retropubic and the TVT-O, but</p> <p>24 could you just remind us just briefly when did the</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. And can you go ahead and open that</p> <p>2 device and let's talk about it briefly.</p> <p>3 A. The first thing that's in the device is</p> <p>4 what's called the Instructions for Use, which we've</p> <p>5 described earlier. This contains information about</p> <p>6 the proper patient that it should be used on or</p> <p>7 what its indications are, who it should not be used</p> <p>8 on, which is contraindications. It describes the</p> <p>9 adverse events and warnings associated with the</p> <p>10 device.</p> <p>11 The TVT-Secur then comes out of the</p> <p>12 package. First, there are guards that are placed</p> <p>13 over the sharp introducer so that the implanting</p> <p>14 surgeon does not get stuck. As you can see on this</p> <p>15 side, it is removed on this end.</p> <p>16 First we see the mesh itself, which is</p> <p>17 the blue mesh. I've described the characteristics</p> <p>18 of the mesh. It is a heavy-weight, small-pore</p> <p>19 mesh, which I've described earlier. The edges are</p> <p>20 cut with the laser, which makes it stiffer and more</p> <p>21 rigid.</p> <p>22 The length is 8 centimeters, which is</p> <p>23 different from the full-length midurethral slings.</p> <p>24 These are the fleece ends that hold the</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 42</p> <p>1 sling in place to provide support for the</p> <p>2 midurethra.</p> <p>3 These are the introducers, which are</p> <p>4 attached to the sharp arrowhead. These are removed</p> <p>5 by disengaging the introducer system so that just</p> <p>6 the fleece tip and the polypropylene material is</p> <p>7 left in place.</p> <p>8 Q. Other than the polypropylene material</p> <p>9 that you've just discussed, had the other design</p> <p>10 characteristics of the TVT-Secur device ever been</p> <p>11 used by Ethicon or any company in the world,</p> <p>12 Doctor?</p> <p>13 MR. SNELL: Objection; asked and answered.</p> <p>14 BY THE WITNESS:</p> <p>15 A. The length of the sling had not been</p> <p>16 used before. The laser cutting had not been used</p> <p>17 before. The sharp arrowhead introducers had not</p> <p>18 been used before and the fleece tips had not been</p> <p>19 used before.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Now, would it assist you in describing</p> <p>22 the procedure and the device to look at a pelvic</p> <p>23 model?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 kind of difficult with all the ends attached. I</p> <p>2 don't want to take them off -- but in a U-shaped</p> <p>3 like this, which is very similar to the -- the</p> <p>4 final position of the TVT Retropubic or out towards</p> <p>5 the sides.</p> <p>6 And this muscle here is called the</p> <p>7 obturator internus muscle. The muscle below it is</p> <p>8 called the levator ani muscle.</p> <p>9 Q. Let me just stop you real quick.</p> <p>10 A. Yes.</p> <p>11 Q. Are the obturator internus muscle and</p> <p>12 the levator ani muscles that you just described</p> <p>13 connected in the pelvic floor?</p> <p>14 A. Yes, they are. There is a line of</p> <p>15 connective tissue that goes between the two of</p> <p>16 them, which is called the arcus tendinea linea</p> <p>17 pelvis. Above that is the obturator internus</p> <p>18 muscle. Below that is the levator muscle.</p> <p>19 The fleece tip goes out towards this</p> <p>20 obturator internus muscle but does not actually</p> <p>21 puncture that obturator internus muscle.</p> <p>22 However, this structure right here is</p> <p>23 called the urogenital diaphragm, and that is</p> <p>24 actually pierced when this is going into the U</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Going to hand you a female pelvic model.</p> <p>2 A. Thank you.</p> <p>3 Q. Can you just describe to the ladies and</p> <p>4 gentlemen of the jury briefly what you're showing</p> <p>5 and what you have in your hands.</p> <p>6 A. Well, this is what's described as the</p> <p>7 bony pelvis, and these are what are called the</p> <p>8 wings of or the iliac crest. This is the pubic</p> <p>9 bone. These are the pubic rami. These are</p> <p>10 actually the bones that we sit on.</p> <p>11 Inside we have the uterus, the bladder</p> <p>12 and way back here is the rectum. We are going to</p> <p>13 kind of take this out for the points or the -- for</p> <p>14 the rest of our discussion about how the TVT-Secur</p> <p>15 device is placed.</p> <p>16 Looking -- these would represent the</p> <p>17 lips of the vagina. This is the opening of the</p> <p>18 vagina. And this would be the urethral opening</p> <p>19 right here.</p> <p>20 So, the TVT-Secur device is placed in</p> <p>21 through a small incision made inside the vagina</p> <p>22 underneath the urethra and then if we look from</p> <p>23 this angle, when it's in place, it can either be</p> <p>24 in -- around the urethra in a U-shaped, and it's</p>	<p style="text-align: right;">Page 45</p> <p>1 position to sit right behind the pubic bone.</p> <p>2 Q. Okay. And if you turn the model around</p> <p>3 at the front, where does, on the front view, where</p> <p>4 does the -- can you show the ladies and gentlemen</p> <p>5 of the jury where the Secur device is implanted</p> <p>6 using the U and the H?</p> <p>7 A. So --</p> <p>8 Q. By "H," I mean the hammock approach.</p> <p>9 A. It's difficult with this. But the U</p> <p>10 would be going in and up and would stay behind the</p> <p>11 pubic bone. The H, it would go in and out and</p> <p>12 would go out towards the obturator internus muscle.</p> <p>13 Q. Now, you -- sorry.</p> <p>14 You had discussed the IFU or the</p> <p>15 Information for Use and you showed that to the</p> <p>16 jury. Can you show them that again, please?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And does the TVT-Secur IFU or</p> <p>19 Information for Use, does that come included in</p> <p>20 every box that is shipped to a doctor?</p> <p>21 A. Yes.</p> <p>22 MR. SNELL: Objection. Hold on. Objection;</p> <p>23 foundation, ship to doctor. Go ahead.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 46	Page 48
<p>1 A. It's shipped to the hospital.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Shipped to the hospital. So, is it</p> <p>4 included -- is the TVT IFU booklet included within</p> <p>5 the box that is shipped to every hospital?</p> <p>6 A. Yes. To be used by the doctor in the</p> <p>7 operating room.</p> <p>8 Q. And does it stay with the TVT-Secur</p> <p>9 product until the doctor opens the TVT-Secur box?</p> <p>10 MR. SNELL: Object; foundation.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Correct.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. In your experience with the TVT devices,</p> <p>15 family of devices, you've implanted some of the</p> <p>16 full-length devices, correct?</p> <p>17 A. Correct, as I've testified to</p> <p>18 previously.</p> <p>19 Q. And did the -- did the IFUs or</p> <p>20 Information for Use related to those devices, were</p> <p>21 those included in the boxes that came from Ethicon?</p> <p>22 A. Yes.</p> <p>23 Q. Did Ethicon ever attach, to your</p> <p>24 knowledge, based on your review of the internal</p>	<p>1 MR. SNELL: Object; leading. Go ahead.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes, I have.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Did you review any other materials</p> <p>6 concerning the implantation of the TVT-Secur</p> <p>7 device?</p> <p>8 A. Yes, I reviewed a training video.</p> <p>9 Q. And would it help you in explaining the</p> <p>10 procedure and the device if we viewed the TVT-Secur</p> <p>11 implant training video?</p> <p>12 A. Yes.</p> <p>13 MR. SNELL: Object; leading. Go ahead.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes, I think that it would be important</p> <p>16 for the jury to be able to understand how the</p> <p>17 device is implanted to be able to see the video.</p> <p>18 MR. THORNBURGH: And let's go ahead and play</p> <p>19 the video. It's Exhibit P1801. But before we do</p> <p>20 that, I'm going to ask --</p> <p>21 MR. SNELL: 1801.</p> <p>22 MR. THORNBURGH: 1801. If the videographer</p> <p>23 could turn the camera and zoom in on the screen so</p> <p>24 that we can view this on video.</p>
Page 47	Page 49
<p>1 documents and your experience, did they ever attach</p> <p>2 any other warnings or instructions other than the</p> <p>3 IFU to the -- to the boxes?</p> <p>4 MR. SNELL: Object; leading. Go ahead.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Not that is not contained in the</p> <p>7 Instructions for Use.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. So, is there any other instruction or</p> <p>10 warnings that come with these products other than</p> <p>11 the IFU?</p> <p>12 A. No.</p> <p>13 MR. SNELL: Objection; overbroad now.</p> <p>14 BY THE WITNESS:</p> <p>15 A. No.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And we are going to talk about the</p> <p>18 Information for Use and labeling and warnings</p> <p>19 throughout today. Okay?</p> <p>20 A. Yes.</p> <p>21 Q. Now, Doctor, in coming here today and in</p> <p>22 forming your opinions, have you also reviewed a</p> <p>23 training video produced by Ethicon on how to</p> <p>24 implant a TVT-Secur in a woman's vagina?</p>	<p>1 THE VIDEOGRAPHER: I just need a moment to</p> <p>2 focus.</p> <p>3 MR. THORNBURGH: No problem.</p> <p>4 MR. SNELL: Perfect. While you're doing that,</p> <p>5 I will put an objection on the record.</p> <p>6 I will object to the showing of the</p> <p>7 video to the jury for the reasons articulated in</p> <p>8 previous trials, including the TVT-Secur trial,</p> <p>9 wherein, one, it's overly graphic and it's not the</p> <p>10 type of material that's intended to be viewed by</p> <p>11 the layperson.</p> <p>12 These are, as I believe the witness</p> <p>13 testified, part of the professional education</p> <p>14 training program for doctors. So they're intended</p> <p>15 for doctors. A jury --</p> <p>16 MR. THORNBURGH: Can I just say -- I'm sorry.</p> <p>17 MR. SNELL: No.</p> <p>18 MR. THORNBURGH: I think the rules say you can</p> <p>19 object. But no speaking objections. I understand</p> <p>20 what you're doing. We understand your position.</p> <p>21 MR. SNELL: I'm laying the foundation.</p> <p>22 MR. THORNBURGH: I'm not saying you are</p> <p>23 waiving your objections. I just want to be able to</p> <p>24 move on and get through this.</p>

13 (Pages 46 to 49)

Bruce Alan Rosenzweig, M.D.

Page 50	Page 52
<p>1 MR. SNELL: As long as you are saying I am not</p> <p>2 waiving it. I was just stating the bases.</p> <p>3 MR. THORNBURGH: I know. I don't think that's</p> <p>4 appropriate in either Federal Court or</p> <p>5 Pennsylvania.</p> <p>6 MR. SNELL: Oh, no, it is, because if this</p> <p>7 was -- this is a trial deposition. If we were</p> <p>8 before the judge, I'd ask for a sidebar and I'd</p> <p>9 make this record right now. But you're saying if</p> <p>10 I'm not waiving it --</p> <p>11 MR. THORNBURGH: Note the objection but you're</p> <p>12 not waiving it if you don't give the basis for your</p> <p>13 objection on this video. Okay?</p> <p>14 MR. SNELL: Okay.</p> <p>15 MR. THORNBURGH: All right.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Okay. So, now, is this the video that</p> <p>18 you review and rely upon in part in formulating</p> <p>19 your opinions in this case?</p> <p>20 A. Yes.</p> <p>21 Q. Now, you testified that one of the</p> <p>22 things that were provided to you when you were</p> <p>23 first introduced to the TVT-Secur product was a</p> <p>24 promotional piece?</p>	<p>1 MR. THORNBURGH: Just say "Objection" and we</p> <p>2 can deal with it later on with the judge.</p> <p>3 MR. SNELL: The problem is I know the bases</p> <p>4 that I'm prepared to assert under Pennsylvania law</p> <p>5 right here and now, and I want to make sure they're</p> <p>6 on the record as opposed to somebody else trying to</p> <p>7 figure out what I was objecting to.</p> <p>8 MR. THORNBURGH: We have done this time and</p> <p>9 time again on videos. We just object and we deal</p> <p>10 with the objections later on. We have this</p> <p>11 agreement, the stipulation in every case.</p> <p>12 MR. SNELL: Actually, we didn't. If you had</p> <p>13 read the Carlino TVT deposition, you saw Mr. Freese</p> <p>14 and I both provided our objections.</p> <p>15 MR. THORNBURGH: Okay. I will just -- I will</p> <p>16 provide long speaking objections on your cross. If</p> <p>17 we're not going to reach an agreement, that's what</p> <p>18 I'll do too.</p> <p>19 MR. SNELL: Okay. You can do whatever you</p> <p>20 want to do.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Doctor, based -- based on your</p> <p>23 discussion and your introduction to the TVT-Secur</p> <p>24 device, what was your understanding of the implant</p>
Page 51	Page 53
<p>1 A. Correct.</p> <p>2 Q. And we're going to look at a lot of</p> <p>3 documents throughout today. But what did Ethicon</p> <p>4 represent to doctors concerning the ease of</p> <p>5 implantation of the TVT-Secur device.</p> <p>6 MR. SNELL: Object to the preface. Objection;</p> <p>7 improper subject matter as to what Ethicon</p> <p>8 represented. This is not an expert on state of</p> <p>9 mind.</p> <p>10 Secondly, this is the material that the</p> <p>11 jury --</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. What was your understanding --</p> <p>14 MR. SNELL: -- can consider for themselves.</p> <p>15 MR. THORNBURGH: Okay. So, you're going to</p> <p>16 give speaking objections rather than just object</p> <p>17 and handle them later on?</p> <p>18 I'm just trying to get through the day</p> <p>19 without having to spend a lot of time listening to</p> <p>20 your -- the basis for your objection.</p> <p>21 MR. SNELL: Yeah, but this is a trial</p> <p>22 deposition. You noticed it as a trial deposition.</p> <p>23 I am giving the basis that I would give to the</p> <p>24 judge.</p>	<p>1 technique?</p> <p>2 A. That it was easy to use and minimally</p> <p>3 invasive.</p> <p>4 Q. And based on your review of the internal</p> <p>5 documents -- strike that.</p> <p>6 Do you have an opinion whether or not</p> <p>7 those representations were accurate?</p> <p>8 A. I do have an opinion.</p> <p>9 Q. What is that opinion, Doctor?</p> <p>10 A. They are not accurate.</p> <p>11 Q. And what's the basis for that opinion,</p> <p>12 Doctor?</p> <p>13 A. The internal documents that I reviewed,</p> <p>14 the training videos that I've looked at and also</p> <p>15 the deposition testimony.</p> <p>16 Q. Okay.</p> <p>17 MR. THORNBURGH: Tom, can you go ahead and hit</p> <p>18 play.</p> <p>19 (Video played.)</p> <p>20 MR. THORNBURGH: Now, go ahead and pause it,</p> <p>21 Tom.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Doctor, what are we seeing here?</p> <p>24 A. This is the initial incision that's made</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 54</p> <p>1 at the level of the midurethra. It is made</p> <p>2 approximately 1 centimeter below the opening of the</p> <p>3 urethra and a cut is made down in through a full</p> <p>4 thickness passage through both the vaginal</p> <p>5 epithelium, the subepithelial tissue into a plane</p> <p>6 that is a full thickness below the vagina and</p> <p>7 before you actually hit the urethral tissue or the</p> <p>8 bladder tissue in a level called the deep</p> <p>9 endopelvic fascia.</p> <p>10 MR. THORNBURGH: Go ahead, Tom.</p> <p>11 BY THE WITNESS:</p> <p>12 A. At this point the surgeon is using</p> <p>13 scissors to create a tunnel. Here the sharp</p> <p>14 arrowhead introducer is being placed into the</p> <p>15 tunnel path that has been created.</p> <p>16 It is being pushed out towards the side.</p> <p>17 This is representing the hammock approach or the H</p> <p>18 approach. And the surgeon is pushing the</p> <p>19 introducer system with the arrowhead on the end out</p> <p>20 towards the obturator internus muscle.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. So, is the doctor who is implanting this</p> <p>23 device pushing the sharp arrowhead introducers</p> <p>24 through the tissue?</p>	<p style="text-align: right;">Page 56</p> <p>1 BY MR. THORNBURGH:</p> <p>2 Q. And, so, we are -- that's it. We're</p> <p>3 good there.</p> <p>4 Now, the introducers, they don't get</p> <p>5 left in the device -- in the body permanently?</p> <p>6 A. No, they do not.</p> <p>7 Q. Okay. Does the Prolene polypropylene</p> <p>8 mesh and fleece mesh remain in the body -- strike</p> <p>9 that.</p> <p>10 Is the TVT-Secur Prolene polypropylene</p> <p>11 mesh material supposed to be left permanently</p> <p>12 inside the human body?</p> <p>13 A. Yes.</p> <p>14 Q. And was the Secur meant to be a</p> <p>15 permanently implanted medical device?</p> <p>16 A. Yes.</p> <p>17 THE VIDEOGRAPHER: Excuse me, counselor. I</p> <p>18 can -- I can photograph capture other exhibits that</p> <p>19 you have on screen if you want them.</p> <p>20 MR. THORNBURGH: Okay.</p> <p>21 THE VIDEOGRAPHER: You can just let me know.</p> <p>22 MR. THORNBURGH: Okay. Thank you. Appreciate</p> <p>23 that.</p> <p>24 MR. SNELL: I think we have an agreement that</p>
<p style="text-align: right;">Page 55</p> <p>1 A. Yes.</p> <p>2 Q. And through muscle?</p> <p>3 A. No, not through muscle. Actually, it's</p> <p>4 going out towards the muscle of the obturator</p> <p>5 internus muscle.</p> <p>6 Q. Okay.</p> <p>7 A. This is when both sides are placed.</p> <p>8 Now, the introducer system is going to</p> <p>9 be removed.</p> <p>10 Right now the doctor is tensioning the</p> <p>11 or attempting to tension the TVT-Secur device at</p> <p>12 the level of the midurethra.</p> <p>13 Q. We're going to talk about tensioning</p> <p>14 throughout today.</p> <p>15 MR. SNELL: Object to counsel's statement. Go</p> <p>16 ahead.</p> <p>17 BY THE WITNESS:</p> <p>18 A. At this point the device is being placed</p> <p>19 in a position to, quote-unquote, "give the proper</p> <p>20 tension" to be able to support the urethra to</p> <p>21 accomplish the action that the device is intended</p> <p>22 to do to stop stress urinary incontinence.</p> <p>23 Now, the introducer is being released.</p> <p>24 This is on the patient's right side.</p>	<p style="text-align: right;">Page 57</p> <p>1 we can put them up when the witness is testifying.</p> <p>2 That's what Rich -- Mr. Freese and I agreed in</p> <p>3 Carlino.</p> <p>4 MR. THORNBURGH: We are going to put them up</p> <p>5 live at trial.</p> <p>6 MR. SNELL: Exactly.</p> <p>7 MR. THORNBURGH: Yeah, that's right.</p> <p>8 MR. SNELL: Okay.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Now, Dr. Rosenzweig, when you treated</p> <p>11 the -- your patients with complications from the</p> <p>12 TVT-Secur device, did you ever have to surgically</p> <p>13 remove the Secur device?</p> <p>14 MR. SNELL: Object; asked and answered,</p> <p>15 repetition.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes, I did.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Does the removal of a mesh or TVT-Secur</p> <p>20 mesh that is causing complications in a patient</p> <p>21 always resolve the problems that the women are</p> <p>22 experiencing?</p> <p>23 MR. SNELL: Objection; compound.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 58	Page 60
<p>1 A. No, it does not.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Even when you remove all the mesh?</p> <p>4 A. Yes.</p> <p>5 Q. Why is that?</p> <p>6 A. As I have described earlier, there is</p> <p>7 often scarring that takes place due to the chronic</p> <p>8 foreign body reaction, chronic inflammatory</p> <p>9 reaction, scar that grows around the mesh that is</p> <p>10 left behind.</p> <p>11 There are nerves that grow through the</p> <p>12 mesh that are injured as the mesh undergoes the</p> <p>13 contraction process that I've described previously.</p> <p>14 Those nerves are permanently injured. And, so, the</p> <p>15 removal of a piece or all of the mesh device does</p> <p>16 not always treat pain, pain with intercourse,</p> <p>17 difficulty voiding, which are the common</p> <p>18 indications for removing the device as I've</p> <p>19 testified to earlier.</p> <p>20 And it's supported in the literature</p> <p>21 that even with complete removal of the device,</p> <p>22 those indications for removing the devices, those</p> <p>23 complications are not always resolved.</p> <p>24 Q. Now, at this point, Doctor, I'd like to</p>	<p>1 Q. Doctor, do you have an opinion --</p> <p>2 Doctor, what are your opinions about the TVT-Secur</p> <p>3 device?</p> <p>4 MR. SNELL: Objection; repetition.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I have already outlined my opinions</p> <p>7 about the TVT-Secur device.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And what is the basis for those</p> <p>10 opinions?</p> <p>11 A. One of the bases for those opinions are</p> <p>12 the internal Ethicon documents.</p> <p>13 Q. And did you bring some of those</p> <p>14 documents with you today?</p> <p>15 A. Yes, I did.</p> <p>16 Q. And are those in front of you?</p> <p>17 A. Yes, they are.</p> <p>18 Q. And would those assist the jury in</p> <p>19 understanding your opinions in this case?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Object; leading.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What is the first internal company</p> <p>24 document that you'd like to discuss with the jury</p>
Page 59	Page 61
<p>1 discuss some of Ethicon's internal company</p> <p>2 documents that you reviewed and relied upon in</p> <p>3 forming your opinions in this case. Okay?</p> <p>4 A. Yes.</p> <p>5 Q. Did you create a binder of the documents</p> <p>6 that you wanted to discuss with the jury?</p> <p>7 A. Yes, I did.</p> <p>8 MR. SNELL: Object; leading. Go ahead.</p> <p>9 This is improper under Pennsylvania</p> <p>10 procedure. Go ahead.</p> <p>11 MR. THORNBURGH: What's improper?</p> <p>12 MR. SNELL: Giving the witness a binder,</p> <p>13 having him take a binder and just start walking</p> <p>14 through.</p> <p>15 MR. THORNBURGH: Both sides did it in both</p> <p>16 prior trials in Pennsylvania.</p> <p>17 MR. SNELL: And I'm sure there were</p> <p>18 objections.</p> <p>19 MR. THORNBURGH: No, no objections.</p> <p>20 MR. SNELL: Yes. In Pennsylvania you ask an</p> <p>21 expert their opinion and then you ask them the</p> <p>22 facts and bases. I shouldn't have to tell you</p> <p>23 that, but that's how it's done.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 today?</p> <p>2 MR. SNELL: Object; leading, improper</p> <p>3 Pennsylvania procedure.</p> <p>4 BY THE WITNESS:</p> <p>5 A. This is an e-mail from October 2002 from</p> <p>6 an Ethicon employee Laura Angelini.</p> <p>7 MR. SNELL: Object.</p> <p>8 MR. THORNBURGH: Hold on one second.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Is it P1553, Doctor?</p> <p>11 A. Yes.</p> <p>12 MR. SNELL: Can I get a copy.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. I am going to hand defense counsel a</p> <p>15 copy of the exhibit.</p> <p>16 Okay. And how does -- how does</p> <p>17 Exhibit P1553 -- strike that.</p> <p>18 First of all, what is the date of the</p> <p>19 e-mail that's Exhibit P1553?</p> <p>20 A. October of 2000.</p> <p>21 Q. Okay. And who is having a discussion</p> <p>22 within this e-mail?</p> <p>23 A. This is from -- to an Ethicon employee,</p> <p>24 Laura Angelini, to other Ethicon employees</p>

16 (Pages 58 to 61)

Bruce Alan Rosenzweig, M.D.

Page 62	Page 64
<p>1 including Dr. Brigitte Hellhammer.</p> <p>2 Q. And how is this document significant to</p> <p>3 your opinions?</p> <p>4 A. This document is significant to my</p> <p>5 opinions as it describes that Ethicon employees did</p> <p>6 not envision ever needing to remove the TVT -- or</p> <p>7 the Prolene mesh after it was placed in the human</p> <p>8 body, first, as an embodiment of the</p> <p>9 TVT Retropubic. Obviously this predates the</p> <p>10 TVT-Secur.</p> <p>11 Q. Okay.</p> <p>12 MR. SNELL: Object. Move to strike.</p> <p>13 Improper -- improper state of mind opinion as to</p> <p>14 what Ethicon people thought.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. What was your understanding when you</p> <p>17 read this document concerning the removal of the</p> <p>18 TVT device and -- and publications concerning the</p> <p>19 removal of the TVT device?</p> <p>20 MR. SNELL: Object; vague.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Well, this is regarding a doctor who is</p> <p>23 going to be writing a paper about needing to remove</p> <p>24 the entire TVT device. Ms. Angelini states, "I do</p>	<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And it's from Brigitte Hellhammer sent</p> <p>4 to an Ethicon employee, a Ms. Waljii and cc'd to</p> <p>5 Dr. Engel Dieter.</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. And it says, "Dear Zenobia," and this is</p> <p>9 Brigitte Hellhammer writing. "Dear Zenobia.</p> <p>10 During his recent visit with us, Professor Klutke</p> <p>11 explained a simple technique to use how to explant</p> <p>12 a Prolene mesh tape, namely by using a normal</p> <p>13 electrocautery device with cutting (not</p> <p>14 coagulating) current."</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. It goes on to say, "The procedure is</p> <p>18 dissect the tape free is simple and quick according</p> <p>19 to Professor Klutke. Although the necessity to</p> <p>20 dissect the tape is extremely rare, this particular</p> <p>21 procedure is interesting, as in early conversation</p> <p>22 with gynecologic surgeons, they told me that</p> <p>23 dissection would be tedious and requires long</p> <p>24 operation time."</p>
Page 63	Page 65
<p>1 not envision any need to explant the TVT."</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Based on your knowledge, training and</p> <p>4 experience, your review of materials that you</p> <p>5 testified you reviewed in this case, is it correct</p> <p>6 that there would not be a need, a clinical -- a</p> <p>7 medical clinical need for the removal of a TVT</p> <p>8 Prolene polypropylene sling device?</p> <p>9 MR. SNELL: Object; leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And who is Dr. Klutke?</p> <p>14 A. Dr. Klutke is a urogynecologist, a</p> <p>15 well-known pelvic surgeon.</p> <p>16 Q. And Dr. Brigitte Hellhammer. Do you</p> <p>17 know who she is?</p> <p>18 A. Yes. She is a scientist at Ethicon.</p> <p>19 Q. And who is Ms. Angelini?</p> <p>20 A. She's in marketing.</p> <p>21 Q. If you turn with me to Exhibit 1553, the</p> <p>22 first e-mail from Brigitte Hellhammer at the bottom</p> <p>23 of the first page. The subject is "Professor</p> <p>24 Klutke" and then it says "Confidential."</p>	<p>1 Did I read that correctly?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And if you -- what is your</p> <p>4 understanding of what was occurring here in 2002</p> <p>5 concerning what Professor Klutke was working on?</p> <p>6 MR. SNELL: Objection; vague.</p> <p>7 BY THE WITNESS:</p> <p>8 A. What Dr. Klutke is describing is a</p> <p>9 technique for being able to remove the mesh that he</p> <p>10 felt would be much quicker and easier, both using</p> <p>11 electrocautery, which is an energy system which not</p> <p>12 only can cut tissue but seal blood vessels, and</p> <p>13 cutting.</p> <p>14 Q. Now, if you turn to the next e-mail in</p> <p>15 this exhibit, Dr. -- there is a Zenobia Waljii.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Who responds to Brigitte Hellhammer and</p> <p>19 she writes, "Dear Briggite, Thanks for your</p> <p>20 thoughts below. In principle I am comfortable with</p> <p>21 you contacting any of the US clinicians. However,</p> <p>22 before you do so, I would really like to understand</p> <p>23 the value of capturing the technique versus some</p> <p>24 potential 'backfire' of this publication."</p>

17 (Pages 62 to 65)

Bruce Alan Rosenzweig, M.D.

Page 66	Page 68
<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Is it ever okay for -- in your opinion,</p> <p>4 is it ever okay -- do you have an opinion one way</p> <p>5 or the other whether it's okay for medical device</p> <p>6 manufacturers of permanently implantable devices to</p> <p>7 withhold a publication because the publication</p> <p>8 could cause a repercussion or consequences to the</p> <p>9 bottom line of the financial stability of the</p> <p>10 product?</p> <p>11 MR. SNELL: Object; improper subject matter.</p> <p>12 That opinion that you're seeking to elicit is not</p> <p>13 explicitly in his Pennsylvania report.</p> <p>14 MR. THORNBURGH: Let me ask a better way.</p> <p>15 MR. SNELL: Secondly --</p> <p>16 MR. THORNBURGH: I'm going to withdraw it. I</p> <p>17 withdraw the question.</p> <p>18 MR. SNELL: Secondly, I object to you reading</p> <p>19 e-mails. That's not how you examine on direct an</p> <p>20 expert in Pennsylvania.</p> <p>21 MR. THORNBURGH: I'm going to withdraw the</p> <p>22 last question. Let me restate it.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Doctor, do you have an opinion whether</p>	<p>1 decide on whether or not they will use a specific</p> <p>2 product.</p> <p>3 Q. And how did -- if you look at</p> <p>4 Exhibit 1553, how did Laura Angelini respond to the</p> <p>5 possibility of Dr. Klutke publishing his technique</p> <p>6 for the removal of TVT midurethral sling?</p> <p>7 MR. SNELL: Object. Reading e-mails by an</p> <p>8 expert, improper subject matter. Jury can read the</p> <p>9 e-mail themselves.</p> <p>10 BY THE WITNESS:</p> <p>11 A. She states, "Frankly, I do not want to</p> <p>12 dig my own grave."</p> <p>13 Q. How is that, if at all, significant to</p> <p>14 your opinions, Doctor?</p> <p>15 A. It's significant to my opinions in that</p> <p>16 a medical device company should want all the</p> <p>17 information, both the good information that</p> <p>18 supports their product plus also the bad</p> <p>19 information that might not support their product or</p> <p>20 does not support their product, to be known by</p> <p>21 doctors so doctors can make informed decisions</p> <p>22 about the use of a product to be able to give that</p> <p>23 information to patients.</p> <p>24 Q. Is Laura Angelini a medical doctor?</p>
Page 67	Page 69
<p>1 companies such as Ethicon and Johnson & Johnson</p> <p>2 should put patient safety before profit?</p> <p>3 A. Yes.</p> <p>4 Q. Why is that?</p> <p>5 A. Because patient safety is paramount.</p> <p>6 Q. And do you have an opinion whether or</p> <p>7 not companies like Ethicon and Johnson & Johnson</p> <p>8 should disclose the good, the bad and the ugly</p> <p>9 concerning products it's selling as permanent</p> <p>10 implantable devices?</p> <p>11 MR. SNELL: Objection; argumentative, outside</p> <p>12 the scope of his expert report as well now.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes, I have an opinion.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. What's that opinion?</p> <p>17 MR. SNELL: This is a jury question too. Go</p> <p>18 ahead.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes, they should.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Why is that?</p> <p>23 A. Because that is information that both</p> <p>24 doctors and patients need in order to be able to</p>	<p>1 A. No.</p> <p>2 MR. SNELL: Object; asked and answered.</p> <p>3 Covered earlier.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What is Laura -- what was Laura</p> <p>6 Angelini's position at Ethicon?</p> <p>7 MR. SNELL: Objection; covered earlier. Go</p> <p>8 ahead.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Marketing.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. So, are you telling the ladies and</p> <p>13 gentlemen of the jury that Laura Angelini, a</p> <p>14 marketing person, is concerned about providing</p> <p>15 safety information to physicians?</p> <p>16 MR. SNELL: Objection; improper state of mind.</p> <p>17 This is outside the scope of his report too. He</p> <p>18 does not --</p> <p>19 MR. THORNBURGH: Just object. Just object.</p> <p>20 MR. SNELL: No, I'm not. I am giving a proper</p> <p>21 trial objection.</p> <p>22 MR. THORNBURGH: What time is it?</p> <p>23 THE VIDEOGRAPHER: 10:24.</p> <p>24 MR. THORNBURGH: Can you look up the</p>

Bruce Alan Rosenzweig, M.D.

Page 70	Page 72
<p>1 Court's -- Judge Greenspan's telephone number? We</p> <p>2 are going to call if we have to. We've done this</p> <p>3 before. You're wasting time.</p> <p>4 MR. SNELL: I'm not wasting your time. I am</p> <p>5 giving a proper objection. You are the one that</p> <p>6 noticed a trial deposition.</p> <p>7 MR. THORNBURGH: Just get Judge Greenspan's</p> <p>8 office, please.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Doctor, do you have an opinion about</p> <p>11 whether or not the marketing person should be</p> <p>12 calling the shots on what safety information is</p> <p>13 provided to physicians?</p> <p>14 MR. SNELL: Object; leading, foundation,</p> <p>15 outside the scope, improper expert subject matter</p> <p>16 now.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I do have an opinion.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What is that?</p> <p>21 A. They should not.</p> <p>22 Q. Doctor, do you know whether or not</p> <p>23 Ethicon ever provided instructions or training on</p> <p>24 how to remove a -- any of its TVT products in the</p>	<p>1 it's appropriate for a person in marketing to</p> <p>2 control the information being published to</p> <p>3 physicians?</p> <p>4 MR. SNELL: Object; leading, foundation,</p> <p>5 outside the scope.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes, I have an opinion.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. What's that opinion?</p> <p>10 A. That is inappropriate.</p> <p>11 Q. Doctor, was the need for a complete</p> <p>12 removal of a TVT device ever common knowledge?</p> <p>13 MR. SNELL: Object. I believe that's outside</p> <p>14 the scope of his report, unless you want to show me</p> <p>15 that opinion.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Do you know, Doctor?</p> <p>18 A. No, it was not common knowledge.</p> <p>19 Q. Was the ability to surgically remove</p> <p>20 these TVT devices ever commonly known?</p> <p>21 MR. SNELL: Same objection; outside the scope.</p> <p>22 BY THE WITNESS:</p> <p>23 A. No.</p> <p>24 BY MR. THORNBURGH:</p>
Page 71	Page 73
<p>1 event of a complication?</p> <p>2 A. No, they did not.</p> <p>3 Q. And is that significant at all to your</p> <p>4 opinions?</p> <p>5 A. Yes.</p> <p>6 Q. What is that?</p> <p>7 A. That if a device is being placed in the</p> <p>8 body permanently, there should be a known,</p> <p>9 reliable, tested method for not only implanting the</p> <p>10 device but also removal of the device.</p> <p>11 Q. Dr. Klutke, is he a medical doctor?</p> <p>12 A. Yes.</p> <p>13 Q. Dr. Hellhammer, is she a medical doctor?</p> <p>14 MR. SNELL: Object; covered.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Ms. Angelini, is she a medical doctor?</p> <p>19 MR. SNELL: Objection; asked and answered</p> <p>20 three times.</p> <p>21 BY THE WITNESS:</p> <p>22 A. No.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Do you have an opinion whether or not</p>	<p>1 Q. Were the -- was it a technique for the</p> <p>2 removal of these TVT products, including the</p> <p>3 TVT-Secur, ever commonly known?</p> <p>4 MR. SNELL: Same objection. Dr. Rosenzweig</p> <p>5 does not have common known opinions in his report.</p> <p>6 Go ahead.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Were you ever trained by Ethicon on the</p> <p>11 proper technique needed to safely remove its TVT</p> <p>12 line of products in the event of complications?</p> <p>13 A. No.</p> <p>14 Q. Prior to your involvement in this</p> <p>15 litigation, were you ever shown this internal</p> <p>16 company document?</p> <p>17 A. No.</p> <p>18 Q. Were doctors in the community, to the</p> <p>19 best of your knowledge and based on your review of</p> <p>20 the internal documents, ever provided with this</p> <p>21 internal Ethicon communication?</p> <p>22 MR. SNELL: Object; outside the scope.</p> <p>23 BY THE WITNESS:</p> <p>24 A. No.</p>

Bruce Alan Rosenzweig, M.D.

Page 74	Page 76
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. What's the next exhibit in your binder</p> <p>3 that you'd like to discuss with the jury?</p> <p>4 A. It's an e-mail from Dr. Axel Arnaud, who</p> <p>5 is a Medical Director, to Dr. Martin Weisberg, also</p> <p>6 a Medical Director, from October of 2002.</p> <p>7 MR. SNELL: Object; improper Pennsylvania</p> <p>8 procedure.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And is this P1080?</p> <p>11 A. Correct.</p> <p>12 Q. And what is the significance of --</p> <p>13 MR. SNELL: Can I have a copy, counsel.</p> <p>14 MR. THORNBURGH: I'm sorry.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. How is this e-mail between Axel Arnaud</p> <p>17 and Marty Weisberg significant, if at all, to your</p> <p>18 opinions in this case?</p> <p>19 A. They're discussing a complication of the</p> <p>20 Prolene mesh called an erosion. I've described</p> <p>21 that earlier for the jury what an erosion is, but</p> <p>22 basically it's when the -- the vagina that is</p> <p>23 covering the mesh dies away and the mesh is now --</p> <p>24 exposes an ulcer into the vagina.</p>	<p>1 wise to be more elusive on this."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. How does that support your opinion,</p> <p>5 Doctor?</p> <p>6 A. It is --</p> <p>7 MR. SNELL: Object; asked and answered. Go</p> <p>8 ahead.</p> <p>9 BY THE WITNESS:</p> <p>10 A. -- improper to be elusive about</p> <p>11 complications associated with a medical device.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Why is it improper to be elusive about</p> <p>14 complications associated with a medical device,</p> <p>15 Doctor?</p> <p>16 A. Because doctors need to be informed</p> <p>17 about that. The manufacturer is the one that has</p> <p>18 the most information, the most resources to know</p> <p>19 about complications associated with their devices</p> <p>20 and they should be frank about discussing that with</p> <p>21 physicians so that physicians know about the</p> <p>22 complications associated with their device.</p> <p>23 Q. Why should physicians know about</p> <p>24 complications associated with medical devices?</p>
Page 75	Page 77
<p>1 And what Dr. Arnaud is stating, that it</p> <p>2 might be wise to be more elusive about this topic</p> <p>3 of mesh erosion.</p> <p>4 Q. Okay. And for the record who is Axel</p> <p>5 Arnaud?</p> <p>6 A. A Medical Director and also a doctor.</p> <p>7 Q. And who is Martin Weisberg?</p> <p>8 A. A Medical Director and also a doctor.</p> <p>9 Q. Do you have an opinion whether or not it</p> <p>10 is okay -- strike that.</p> <p>11 Do you have an opinion whether or not</p> <p>12 being elusive about safety information is proper?</p> <p>13 A. I do have an opinion.</p> <p>14 Q. What's that opinion?</p> <p>15 A. It is not proper.</p> <p>16 Q. And go ahead and highlight for us the</p> <p>17 first paragraph here.</p> <p>18 It says, "Dear Doctor, I reviewed your</p> <p>19 draft report. Apart from minor corrections</p> <p>20 concerning typing errors, it is perfect for me. I</p> <p>21 just had a concern about your statement concerning</p> <p>22 potential complications/fistula and erosions. This</p> <p>23 is a problem which arises rather commonly in</p> <p>24 practice even with polypropylene and it might be</p>	<p>1 A. So that they can discuss that with their</p> <p>2 patients so that the patient can ultimately make an</p> <p>3 informed decision about the treatment that they</p> <p>4 get, the devices that are being used. It's</p> <p>5 ultimately up to the patient to make the decision</p> <p>6 about the treatment that she has and which devices</p> <p>7 will be used to accomplish that treatment.</p> <p>8 Q. Do you have an opinion about whether or</p> <p>9 not -- do you have an opinion about what could</p> <p>10 happen to patients if medical device companies are</p> <p>11 elusive about safety information?</p> <p>12 MR. SNELL: Objection; outside the scope of</p> <p>13 his report. Not an opinion he's expressed.</p> <p>14 BY THE WITNESS:</p> <p>15 A. That patient safety is compromised.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. What does that mean, "patient safety is</p> <p>18 compromised"?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That patients unfortunately would be</p> <p>22 exposed to complications that they might not be</p> <p>23 exposed to. Quite frankly, the patients would end</p> <p>24 up getting the short end of the stick.</p>

20 (Pages 74 to 77)

Bruce Alan Rosenzweig, M.D.

Page 78	Page 80
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. What's the next document you'd like to</p> <p>3 discuss with the jury today?</p> <p>4 MR. SNELL: Object; improper Pennsylvania</p> <p>5 procedure. Can I have a copy?</p> <p>6 BY THE WITNESS:</p> <p>7 A. This is an e-mail from Medical Director</p> <p>8 Axel Arnaud to several key Ethicon employees,</p> <p>9 including engineer Gene Kammerer.</p> <p>10 MR. SNELL: Give me a second, Doctor. Before</p> <p>11 we go reading. Okay.</p> <p>12 MR. THORNBURGH: I don't know if I did this.</p> <p>13 But let's go ahead and mark the entire binder as</p> <p>14 Exhibit BR-Secur 5.</p> <p>15 (WHEREUPON, a binder was marked as</p> <p>16 BR-Secur Exhibit No. 5: Binder of</p> <p>17 various Plaintiffs' Exhibits</p> <p>18 referred to by deponent.)</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Okay. So, you were discussing</p> <p>21 Exhibit P933, which is within Exhibit 5, the</p> <p>22 binder.</p> <p>23 How is Exhibit P0933 -- strike that.</p> <p>24 Is -- did you rely on Exhibit -- strike</p>	<p>1 intercourse, obstruction of voiding and mesh</p> <p>2 erosion.</p> <p>3 Q. Now, we'll get to the Information for</p> <p>4 Use in a little bit in greater detail. But did</p> <p>5 Ethicon ever indicate in the Information for Use</p> <p>6 for the TVT-Secur device that the TVT-Secur device,</p> <p>7 once implanted, could shrink up to 30%?</p> <p>8 A. No, they did not.</p> <p>9 Q. Doctor, based on your review of the</p> <p>10 internal documents, did Ethicon -- strike that.</p> <p>11 Did Ethicon -- do you have an opinion --</p> <p>12 strike that.</p> <p>13 Do you have an opinion whether or not</p> <p>14 Ethicon ever disclosed to the world or to</p> <p>15 physicians that their TVT line of products could</p> <p>16 shrink up to 30%?</p> <p>17 A. No.</p> <p>18 MR. SNELL: Objection; outside the scope of</p> <p>19 the report.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What's the basis for that opinion,</p> <p>24 Doctor?</p>
Page 79	Page 81
<p>1 that.</p> <p>2 Did you rely on Exhibit P0933?</p> <p>3 A. Yes.</p> <p>4 Q. And how does Exhibit P0933 support your</p> <p>5 opinions in this case?</p> <p>6 A. This document describes e-mail between</p> <p>7 key Ethicon employees and it documents that</p> <p>8 Dr. Axel Arnaud knew that mesh contracted or shrank</p> <p>9 30%.</p> <p>10 MR. SNELL: Object; improper state of mind</p> <p>11 opinion.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And how is shrinkage, a 30% shrinkage --</p> <p>14 strike that.</p> <p>15 How is the fact that Axel Arnaud writes</p> <p>16 or agrees that shrinkage can occur up to 30% of an</p> <p>17 implanted TVT mesh relevant to your opinions?</p> <p>18 A. I've already described the importance of</p> <p>19 mesh contraction, deformation caused by the chronic</p> <p>20 foreign body reaction, chronic inflammatory</p> <p>21 reaction.</p> <p>22 A 30% shrinkage is a significant degree</p> <p>23 of shrinkage and will lead to complications that</p> <p>24 I've described before, such as pain, pain with</p>	<p>1 A. The review of internal documents and</p> <p>2 deposition testimony.</p> <p>3 Q. Doctor, when was the first time you</p> <p>4 learned that the TVT products, including the TVT-R,</p> <p>5 Retropubic, the TVT-O, Obturator, or the TVT-S, the</p> <p>6 Secur, could shrink up to 30% after implant in the</p> <p>7 human body?</p> <p>8 Did you know this before you became</p> <p>9 involved as an expert in this litigation?</p> <p>10 A. I understood that from the literature</p> <p>11 that there could be mesh contraction.</p> <p>12 Q. Did you understand that Ethicon was</p> <p>13 aware that up to 30% of its meshes -- 30% of the</p> <p>14 TVT device -- devices could retract or shrink?</p> <p>15 MR. SNELL: Objection; misstates the evidence,</p> <p>16 state of mind as to Ethicon.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I had not seen this e-mail prior to</p> <p>19 becoming involved in this litigation.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Did Ethicon share this e-mail with</p> <p>22 anybody outside of Ethicon?</p> <p>23 MR. SNELL: Objection; improper opinion.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 82	Page 84
<p>1 A. No.</p> <p>2 MR. SNELL: Outside the scope.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Was it common knowledge in the medical</p> <p>5 community that the TVT devices, including the</p> <p>6 TVT-Secur, could shrink up to 30%?</p> <p>7 MR. SNELL: Object; outside the scope.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Was it disclosed outside of Ethicon by</p> <p>12 Ethicon to physicians that their TVT devices,</p> <p>13 including the TVT-Secur, could shrink up to 30%?</p> <p>14 MR. SNELL: Objection; outside the report.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. How is this document significant to your</p> <p>19 opinions?</p> <p>20 A. That this describes the scientific</p> <p>21 knowledge of the Medical Director and the</p> <p>22 discussion among key Ethicon employees regarding</p> <p>23 the rate of shrinkage or the degree of shrinkage of</p> <p>24 a TVT device.</p>	<p>1 Q. What is the next document that you'd</p> <p>2 like to discuss with the ladies and gentlemen of</p> <p>3 the jury and how does it support your opinions?</p> <p>4 MR. SNELL: Object; improper Pennsylvania</p> <p>5 procedure. Go ahead.</p> <p>6 BY THE WITNESS:</p> <p>7 A. This is an e-mail which is from</p> <p>8 December of 2004.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And for the record just identify the</p> <p>11 exhibit number.</p> <p>12 MR. SNELL: Can I get a copy too.</p> <p>13 MR. THORNBURGH: I'm sorry.</p> <p>14 BY THE WITNESS:</p> <p>15 A. It is P1572.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Okay. And what is this document?</p> <p>18 A. It is an e-mail. Attached to it is</p> <p>19 what's called the charter document which -- for</p> <p>20 what was described as the TVT X. TVT X is the code</p> <p>21 name, if you will, during the development phase of</p> <p>22 the TVT-Secur before it became the TVT-Secur.</p> <p>23 And it is -- the charter document is a</p> <p>24 document to describe to management why they should</p>
Page 83	Page 85
<p>1 MR. SNELL: Improper state of mind. Object.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. What can happen to patients if the mesh</p> <p>4 shrinks up to 30%?</p> <p>5 A. As I've described in prior testimony,</p> <p>6 mesh contraction up to this degree can lead to</p> <p>7 complications such as pain, pain with intercourse,</p> <p>8 mesh erosion, and obstructed voiding.</p> <p>9 MR. THORNBURGH: Take a quick break.</p> <p>10 THE VIDEOGRAPHER: Okay. The time is 10:39</p> <p>11 a.m. This is the end of Tape 1 and we are going</p> <p>12 off the video record.</p> <p>13 (WHEREUPON, a recess was had</p> <p>14 from 10:39 to 10:48 a.m.)</p> <p>15 THE VIDEOGRAPHER: The time is 10:48 a.m.</p> <p>16 This is the beginning of Tape 2 and we're back on</p> <p>17 the video record.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Doctor, before we went off the record we</p> <p>20 were talking about your opinions, summary of</p> <p>21 opinions that you provided earlier and the bases</p> <p>22 for those opinions including the internal documents</p> <p>23 that you have shown us so far?</p> <p>24 A. Yes.</p>	<p>1 go forward with the TVT X project.</p> <p>2 Q. Okay. And how does this document --</p> <p>3 strike that.</p> <p>4 What is significant about Exhibit P1527?</p> <p>5 A. Well, this is from the project leader</p> <p>6 Dan Smith. Dan Smith is an engineer at Ethicon.</p> <p>7 And this describes the annual sales for the current</p> <p>8 products, the TVT and the TVT-O. It's estimated to</p> <p>9 reach 100 million by the end of 2004 with a 91%</p> <p>10 profitability, that the new product that is being</p> <p>11 described in this charter document, the TVT X,</p> <p>12 which ultimately became the TVT-Secur, will help</p> <p>13 Gynecare and Ethicon maintain their market</p> <p>14 dominance. However, it is important for them to</p> <p>15 stay ahead of --</p> <p>16 Q. Go ahead.</p> <p>17 A. -- the competition and that being the</p> <p>18 first to market with a new device such as the TVT X</p> <p>19 would be, quote-unquote, "priceless."</p> <p>20 Q. Now --</p> <p>21 MR. SNELL: Object. Object. Move to strike</p> <p>22 the entire answer as non-responsive and improper</p> <p>23 subject matter.</p> <p>24 BY MR. THORNBURGH:</p>

22 (Pages 82 to 85)

Bruce Alan Rosenzweig, M.D.

Page 86	Page 88
<p>1 Q. Now, Doctor, is it improper for a</p> <p>2 medical device company to want to be first to</p> <p>3 market?</p> <p>4 MR. SNELL: Object; state of mind, outside the</p> <p>5 scope of the report.</p> <p>6 BY THE WITNESS:</p> <p>7 A. It is not improper to want to be the</p> <p>8 first to market.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And -- and when does it become improper?</p> <p>11 MR. SNELL: Same objection.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Does it ever -- strike that.</p> <p>14 Does it ever become improper?</p> <p>15 MR. SNELL: Same objections, requires --</p> <p>16 sorry. Lacks foundation.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes, it does.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And when is that?</p> <p>21 A. When a product is not adequately tested</p> <p>22 prior to it being launched to be able to understand</p> <p>23 the safety and efficacy of the product prior to</p> <p>24 being launched.</p>	<p>1 Q. What, if anything, should a company do</p> <p>2 if it determines prior to launch that its product</p> <p>3 is not efficacious or is unsafe?</p> <p>4 A. They should not launch the product.</p> <p>5 Q. Is it ever okay for a company such as</p> <p>6 Ethicon and Johnson & Johnson to be motivated by</p> <p>7 profits over providing safe and effective care and</p> <p>8 treatment to patients?</p> <p>9 MR. SNELL: Object; improper expert opinion,</p> <p>10 state of mind.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No, it is not.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Why is that?</p> <p>15 A. Because then patient safety is</p> <p>16 compromised and patients would be exposed to an</p> <p>17 undue amount of complications.</p> <p>18 Q. Okay. And, so, if we look at the</p> <p>19 Exhibit P1527 and go to ETH.MESH.07898854, which is</p> <p>20 the first page of the attachment of the e-mail.</p> <p>21 And I think this describes some of what</p> <p>22 you've just testified about. This is the charter</p> <p>23 document, is that correct?</p> <p>24 A. Correct.</p>
Page 87	Page 89
<p>1 Q. Fair enough. So, it's -- I think if I</p> <p>2 understand you correctly, it's okay to be first to</p> <p>3 market with your product as long as you do it in an</p> <p>4 appropriate way?</p> <p>5 MR. SNELL: Objection; leading.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Is that correct?</p> <p>8 A. Correct.</p> <p>9 MR. SNELL: Leading, repetition.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And to do it, what needs to be done in</p> <p>12 order to become -- to bring your product and be the</p> <p>13 first to market in a way that also provides safety</p> <p>14 for patients?</p> <p>15 MR. SNELL: Overbroad.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. That also considers safety for patients?</p> <p>18 MR. SNELL: Object; overbroad.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Product has to be designed, evaluated</p> <p>21 and tested in order to make sure that the</p> <p>22 characteristics of the device are safe and that the</p> <p>23 device performs as it's intended.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 Q. And who is Dan Smith?</p> <p>2 A. Dan Smith is an engineer and the project</p> <p>3 leader for the TVT X project, which ultimately</p> <p>4 became the TVT-Secur.</p> <p>5 Q. Was Dan Smith a medical doctor?</p> <p>6 A. No.</p> <p>7 Q. Was Dan Smith a gynecologist?</p> <p>8 A. No.</p> <p>9 Q. Was Dan Smith a urogynecologist?</p> <p>10 A. No.</p> <p>11 Q. Who invented the TVT-Secur?</p> <p>12 A. Dan Smith was one of the -- was the lead</p> <p>13 engineer on the TVT-Secur project.</p> <p>14 Q. And this document says that the "annual</p> <p>15 sales of the Gynecare TVT brand (TVT and TVT-O) in</p> <p>16 the direct markets is estimated to reach somewhere</p> <p>17 around \$100 million by the end of 2004 with a</p> <p>18 profitability of around 91%."</p> <p>19 Did I read that correctly?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yes.</p> <p>23 MR. SNELL: Leading and improper expert</p> <p>24 subject matter. The jury can read an e-mail for</p>

Bruce Alan Rosenzweig, M.D.

Page 90	Page 92
<p>1 themselves.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. If you go down to the last sentence in</p> <p>4 the first -- in this first section it says, "It</p> <p>5 remains strongly recognized that Gynecare developed</p> <p>6 this market and coupled with the skills,</p> <p>7 competencies and capabilities within the</p> <p>8 organization, such market dominance can be</p> <p>9 sustained. However, product innovation and</p> <p>10 advancement is required in order to stay ahead of</p> <p>11 the competition."</p> <p>12 Did I read that correctly?</p> <p>13 A. Yes.</p> <p>14 MR. SNELL: Object; leading, improper expert</p> <p>15 subject matter. The jury can read documents</p> <p>16 themselves.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And is it improper to try to stay ahead</p> <p>19 of competition?</p> <p>20 A. No.</p> <p>21 Q. Does it ever become improper?</p> <p>22 A. If --</p> <p>23 MR. SNELL: Object; vague, overbroad.</p> <p>24 BY THE WITNESS:</p>	<p>1 it and it's asked and answered, repetition.</p> <p>2 MR. THORNBURGH: Could you try not to speak</p> <p>3 over me or object over the question or the answer.</p> <p>4 MR. SNELL: I'm not trying to object over the</p> <p>5 answer.</p> <p>6 MR. THORNBURGH: We have to cut this later on.</p> <p>7 MR. SNELL: I know. I'm trying to wait for</p> <p>8 you to finish. But please give me a break, sir.</p> <p>9 THE WITNESS: Yes, sir.</p> <p>10 MR. SNELL: I know. I don't mean to step on</p> <p>11 you at all. I just need to -- I have to get my</p> <p>12 objection in.</p> <p>13 I'll try to wait until you finish, Dan.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Is the TVT-Secur a permanent implantable</p> <p>16 device?</p> <p>17 MR. SNELL: Object; repetition, asked and</p> <p>18 answered.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. In light of that fact, would it be</p> <p>23 proper for Ethicon to rush a product to the</p> <p>24 market --</p>
Page 91	Page 93
<p>1 A. If a device is not properly tested to</p> <p>2 assure that it is safe and effective.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And what can happen to patients if</p> <p>5 devices aren't properly tested?</p> <p>6 A. Patients are exposed --</p> <p>7 MR. SNELL: Objection; requires speculation</p> <p>8 without foundation.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Patients are exposed to risks of safety</p> <p>11 or in -- or lack of efficacy of the product that</p> <p>12 they are being used that is permanently implanted</p> <p>13 product that is supposed to be in them for the rest</p> <p>14 of their lives.</p> <p>15 Q. This is a permanent -- TVT-Secur is a</p> <p>16 permanent implantable device, right?</p> <p>17 A. Right.</p> <p>18 MR. SNELL: Object. Hold on. Leading.</p> <p>19 MR. THORNBURGH: He already testified --</p> <p>20 MR. SNELL: Leading, asked and answered three</p> <p>21 times. Go ahead.</p> <p>22 MR. THORNBURGH: It's not leading if he's</p> <p>23 already testified to it.</p> <p>24 MR. SNELL: No, it's leading. You're stating</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. -- without properly testing it?</p> <p>4 A. No.</p> <p>5 Q. This is serious business, isn't it?</p> <p>6 MR. SNELL: Object; leading, argumentative.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Is this serious business?</p> <p>9 A. Yes.</p> <p>10 Q. This is a serious issue that we are</p> <p>11 talking about here?</p> <p>12 A. Yes.</p> <p>13 Q. Is the health and well-being of women</p> <p>14 important?</p> <p>15 A. Yes.</p> <p>16 Q. Should companies consider the health and</p> <p>17 well-being to be important?</p> <p>18 MR. SNELL: Object; repetition.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Strike that.</p> <p>21 Should companies like Ethicon and</p> <p>22 Johnson & Johnson who develop medical devices for</p> <p>23 women consider the safety and well-being of women</p> <p>24 to be important?</p>

Bruce Alan Rosenzweig, M.D.

Page 94	Page 96
<p>1 A. Yes.</p> <p>2 MR. SNELL: Object; repetition.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What happens if a company like Ethicon</p> <p>5 and Johnson & Johnson doesn't consider the health</p> <p>6 and well-being of women to be important?</p> <p>7 MR. SNELL: Object; state of mind, repetition.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Women suffer.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Should the health and well-being of</p> <p>12 women be more important than beating your</p> <p>13 competition to market --</p> <p>14 MR. SNELL: Object.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. -- with a product?</p> <p>17 MR. SNELL: Object; repetition.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Should the health and well-being of</p> <p>22 women be more important to a company like Ethicon</p> <p>23 and Johnson & Johnson than how much money you're</p> <p>24 going to make on a given product in a given year?</p>	<p>1 Q. Now, in this charter document, if you</p> <p>2 turn to -- if you go to the last bullet point on</p> <p>3 ETH.MESH ending in 854, it says, "Being first to</p> <p>4 market with a superior less-invasive TVT product</p> <p>5 and protecting our market share could be</p> <p>6 priceless."</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes.</p> <p>9 Q. And is that what you testified to</p> <p>10 earlier?</p> <p>11 A. Yes.</p> <p>12 Q. And if we turn to ETH.MESH.07898856 of</p> <p>13 Exhibit P1527, is there anything significant about</p> <p>14 this next page?</p> <p>15 A. This is a page has a graphic that</p> <p>16 describes what Gynecare or -- Gynecare is a</p> <p>17 division of Ethicon -- what their market share</p> <p>18 would be without having the TVT X as part of their</p> <p>19 sales armamentarium.</p> <p>20 Q. And if you look at the second bullet</p> <p>21 point, there is a graph underneath that second</p> <p>22 bullet point. Is that the graph that you're</p> <p>23 referring to?</p> <p>24 A. Yes.</p>
Page 95	Page 97
<p>1 MR. SNELL: Object; improper expert opinion.</p> <p>2 Outside the scope of this medical doctor's report.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Why is that, Doctor?</p> <p>7 A. Because the safety of the patient is</p> <p>8 paramount.</p> <p>9 Q. Do you have an opinion based on your</p> <p>10 review -- do you have an opinion whether or not</p> <p>11 Ethicon put patient safety before profits?</p> <p>12 MR. SNELL: Objection; state of mind, improper</p> <p>13 expert testimony, outside the scope.</p> <p>14 BY THE WITNESS:</p> <p>15 A. For the TVT-Secur, yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. What's that opinion?</p> <p>18 MR. SNELL: Same.</p> <p>19 BY THE WITNESS:</p> <p>20 A. They put profits before patient safety.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What's the basis for that opinion?</p> <p>23 A. The internal documents, the testimony of</p> <p>24 key Ethicon employees.</p>	<p>1 Q. And what does it show would happen to</p> <p>2 the Gynecare market share without the TVT-Secur?</p> <p>3 MR. SNELL: Object; improper expert testimony.</p> <p>4 BY THE WITNESS:</p> <p>5 A. There would be --</p> <p>6 MR. SNELL: The jury can discern this for</p> <p>7 themselves.</p> <p>8 BY THE WITNESS:</p> <p>9 A. There would be a steady decline in their</p> <p>10 market share from approximately the high 60s to the</p> <p>11 low teens.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And just above this graph it says, the</p> <p>14 last sentence, "It is anticipated that there will</p> <p>15 be at least two competitor mini-type devices</p> <p>16 launched in 2006."</p> <p>17 Did I read that correctly?</p> <p>18 MR. SNELL: Object; leading, reading document.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What's the significance of that</p> <p>23 statement with respect to your opinions?</p> <p>24 MR. SNELL: Object; undisclosed opinion,</p>

25 (Pages 94 to 97)

Bruce Alan Rosenzweig, M.D.

Page 98	Page 100
<p>1 outside the scope, improper expert opinion under</p> <p>2 Pennsylvania Rule 702.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Go ahead, Doctor.</p> <p>5 A. If there are competitors that are on the</p> <p>6 market, they -- the competitors would take market</p> <p>7 share away from Ethicon's devices.</p> <p>8 Q. And if you turn to -- it's page 4 of the</p> <p>9 attachment to Exhibit P27 or ETH.MESH.07898857, and</p> <p>10 tell us what is significant to your opinions on</p> <p>11 this page, if anything.</p> <p>12 A. These are -- this page describes</p> <p>13 critical assumptions that were made during the</p> <p>14 planning to decide if they are going to actually go</p> <p>15 ahead and make the device which ultimately became</p> <p>16 the TVT-Secur. These critical assumptions, if they</p> <p>17 are found to be incorrect during the design, the</p> <p>18 development and the testing of the product, would</p> <p>19 mean that this would be a, quote, "no-go decision"</p> <p>20 or they would decide against bringing this product</p> <p>21 to market.</p> <p>22 And this is a list of what would be, if</p> <p>23 these assumptions are wrong, they would not go</p> <p>24 ahead with the product.</p>	<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And how is that statement, if at all,</p> <p>4 important to your opinions?</p> <p>5 A. That the decision that was made in</p> <p>6 December of 2004 was that if the TVT X, which</p> <p>7 ultimately became the TVT-Secur, if it was found to</p> <p>8 have a lower effectiveness as compared to the</p> <p>9 full-length TVT products, then they would not go</p> <p>10 ahead with the project.</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. And they would not launch the product.</p> <p>14 MR. SNELL: Object. Sorry, Doctor.</p> <p>15 THE WITNESS: It's okay.</p> <p>16 MR. SNELL: Object. Move to strike.</p> <p>17 Misstates the evidence and the document itself.</p> <p>18 Improper opinion.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Let me understand this correctly,</p> <p>21 Doctor.</p> <p>22 Are you telling me and the ladies and</p> <p>23 gentlemen of this jury that Ethicon -- that it was</p> <p>24 Ethicon's position that if they had found or</p>
Page 99	Page 101
<p>1 MR. SNELL: Object; improper state of mind,</p> <p>2 improper expert opinion.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. So, if we look at the third bullet point</p> <p>5 on this page ending in 857 of Exhibit 1527, it</p> <p>6 says, "Critical Assumptions," and I think this is</p> <p>7 what you just summarized, but it says, "Critical</p> <p>8 Assumptions. What are the assumptions about the</p> <p>9 project, which if incorrect, could result in a</p> <p>10 no-go decision?"</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes.</p> <p>13 MR. SNELL: Object; leading, reading</p> <p>14 documents.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And the first assumption, first bullet</p> <p>17 point under this list says, "Shorter mesh implanted</p> <p>18 will provide equivalent efficacy compared to</p> <p>19 current mesh length and position in both the</p> <p>20 retropubic and obturator direction."</p> <p>21 Did I read that correctly?</p> <p>22 MR. SNELL: Objection; leading, reading</p> <p>23 document to an expert on direct, improper.</p> <p>24 BY THE WITNESS:</p>	<p>1 determined that the TVT-Secur was not as effective</p> <p>2 as their full-length midurethral slings like the</p> <p>3 TVT or the TVT-O that were already on the market</p> <p>4 before they launched it, that Ethicon would not</p> <p>5 launch the TVT-Secur device?</p> <p>6 MR. SNELL: Objection; improper, state of mind</p> <p>7 opinion, outside the scope of his report and also</p> <p>8 misstates the document itself. Go ahead.</p> <p>9 MR. THORNBURGH: You know what? Hold on a</p> <p>10 second. Call the judge. I am tired of every</p> <p>11 objection -- every question you have objected to.</p> <p>12 I am tired of it.</p> <p>13 MR. SNELL: That's okay.</p> <p>14 MR. THORNBURGH: You're wasting my time and</p> <p>15 you're interfering with the flow of the deposition</p> <p>16 and they are improper objections. So, let's get</p> <p>17 the judge on the phone.</p> <p>18 Is there a conference phone?</p> <p>19 MS. LaPOINTE: No.</p> <p>20 THE VIDEOGRAPHER: Shall I stay on the record</p> <p>21 or go off?</p> <p>22 MR. THORNBURGH: You can go off until we get</p> <p>23 her on. We will keep the Court Reporter on the</p> <p>24 record.</p>

Bruce Alan Rosenzweig, M.D.

Page 102	Page 104
<p>1 THE WITNESS: I will step out of the room. I</p> <p>2 think it's probably more appropriate if I do.</p> <p>3 THE VIDEOGRAPHER: The time is 11:06 a.m. and</p> <p>4 I'm going off the video record.</p> <p>5 (WHEREUPON, the deponent exited the</p> <p>6 proceedings.)</p> <p>7 (WHEREUPON, Bobby (Brad) Bradford,</p> <p>8 Esq. entered the proceedings.)</p> <p>9 (WHEREUPON, the following</p> <p>10 proceedings were had off the video</p> <p>11 record in a conference call with</p> <p>12 Justice Greenspan:)</p> <p>13 HUNTER: Thank you for calling JAMS. This is</p> <p>14 Hunter.</p> <p>15 MR. THORNBURGH: Hi, Hunter. My name is Dan</p> <p>16 Thornburgh. I'm here in a deposition with defense</p> <p>17 counsel in the matter of Ebaugh vs. Ethicon and</p> <p>18 Johnson & Johnson and we have kind of a discovery</p> <p>19 issue or dispute that I'd like to, if possible, get</p> <p>20 some guidance from Judge Greenspan.</p> <p>21 HUNTER: Okay. Just one second. I will see</p> <p>22 if I can get ahold of her.</p> <p>23 MR. THORNBURGH: Thank you. I appreciate it.</p> <p>24 HUNTER: You're welcome.</p>	<p>1 JUSTICE GREENSPAN: Right now?</p> <p>2 MR. THORNBURGH: In a deposition right now in</p> <p>3 the matter of Ebaugh vs. Ethicon and</p> <p>4 Johnson & Johnson. It's another TVT-Secur case.</p> <p>5 JUSTICE GREENSPAN: Right. One of the pelvic</p> <p>6 mesh cases.</p> <p>7 MR. THORNBURGH: Yes, correct.</p> <p>8 JUSTICE GREENSPAN: And somebody -- who is the</p> <p>9 witness? What's his position?</p> <p>10 MR. THORNBURGH: The witness is Dr. Bruce</p> <p>11 Rosenzweig. He is --</p> <p>12 JUSTICE GREENSPAN: I know, yes.</p> <p>13 MR. THORNBURGH: He's Plaintiffs' general</p> <p>14 liability and causation expert witness and we are</p> <p>15 at a preservation --</p> <p>16 JUSTICE GREENSPAN: Right, I know</p> <p>17 Dr. Rosenzweig.</p> <p>18 MR. THORNBURGH: We are at this preservation</p> <p>19 deposition and with every question that I ask, and,</p> <p>20 look, I'm doing my best to ask the best questions I</p> <p>21 can, but every question I get I'm getting objected</p> <p>22 to, not just an objection, but a speaking objection</p> <p>23 by defense counsel and it's interrupting the flow</p> <p>24 of the deposition.</p>
Page 103	Page 105
<p>1 JUSTICE GREENSPAN: Hello.</p> <p>2 MR. THORNBURGH: Hi. Is this Justice</p> <p>3 Greenspan?</p> <p>4 JUSTICE GREENSPAN: This is she.</p> <p>5 MR. THORNBURGH: Hi, Justice Greenspan. This</p> <p>6 is Dan Thornburgh with Aylstock, Witkin, Kreis &</p> <p>7 Overholtz.</p> <p>8 JUSTICE GREENSPAN: Hi Dan, how are you?</p> <p>9 MR. THORNBURGH: Good. How are you doing?</p> <p>10 JUSTICE GREENSPAN: Okay.</p> <p>11 MR. THORNBURGH: Good. I am here with defense</p> <p>12 counsel for Ethicon.</p> <p>13 MR. SNELL: Hi, Justice Greenspan. It's Burt</p> <p>14 Snell from Butler Snow.</p> <p>15 MR. THORNBURGH: The reason for the call, your</p> <p>16 Honor, is we are in a de bene esse preservation</p> <p>17 trial deposition and with every question that I</p> <p>18 ask, I get a -- to the witness, I get a speaking</p> <p>19 objection from defense counsel, almost every single</p> <p>20 question, 99% of the questions. And I tried to</p> <p>21 reach an agreement --</p> <p>22 JUSTICE GREENSPAN: I'm sorry. Dan, run that</p> <p>23 by me again. You are in a deposition.</p> <p>24 MR. THORNBURGH: Yes.</p>	<p>1 It's interrupting the way I want, you</p> <p>2 know, I want this deposition to move forward</p> <p>3 quickly and as efficiently as possible. I have</p> <p>4 tried to reach an agreement with counsel that they</p> <p>5 can just object without speaking objection without</p> <p>6 waiving, other than leading.</p> <p>7 Generally how we do this is if there is</p> <p>8 an objection, you say "Objection" without giving</p> <p>9 the basis for the objection so that it doesn't</p> <p>10 interrupt or interfere with the flow of the</p> <p>11 deposition, the questions that are being asked by</p> <p>12 counsel, the strategies that are involved. And</p> <p>13 those issues can be resolved later on.</p> <p>14 But I am getting interruption with these</p> <p>15 speaking objections almost every single question I</p> <p>16 ask. And all I'm saying, all I'm asking is counsel</p> <p>17 just say "Objection" unless it's leading. Then he</p> <p>18 can say "Objection; leading," which is the way we</p> <p>19 have done this in other case. And he's refused to</p> <p>20 do that and it's interrupting the flow.</p> <p>21 JUSTICE GREENSPAN: Who is defense counsel?</p> <p>22 MR. SNELL: Judge, it's Burt Snell. You and I</p> <p>23 know each other very well. I am the one who</p> <p>24 crossed Dr. Rosenzweig --</p>

Bruce Alan Rosenzweig, M.D.

Page 106	Page 108
<p>1 JUSTICE GREENSPAN: Okay.</p> <p>2 MR. SNELL: -- in his prior de bene esse.</p> <p>3 JUSTICE GREENSPAN: What's going on here? Why</p> <p>4 can't you just make an objection and leave it at</p> <p>5 that?</p> <p>6 MR. SNELL: Well, one, Justice, that's not how</p> <p>7 we did this. This is a trial de bene esse</p> <p>8 deposition. This is not some discovery deposition.</p> <p>9 I took his de bene esse TVT deposition,</p> <p>10 and I made these similar type objections when there</p> <p>11 was improper questioning as to expert subject</p> <p>12 matter.</p> <p>13 To put things into context, Justice</p> <p>14 Greenspan, I'm not objecting to every question but</p> <p>15 when the Plaintiffs' counsel is asking</p> <p>16 Dr. Rosenzweig "What was Ethicon thinking" and</p> <p>17 "Would it be right for a manufacturer to ever think</p> <p>18 this," that's all improper expert subject matter</p> <p>19 and state of mind.</p> <p>20 So, the majority of my opinions have</p> <p>21 been on state of mind, expert improper opinion; and</p> <p>22 this is basically an exam that's not comporting</p> <p>23 with the Pennsylvania rules from my perspective.</p> <p>24 So, that's where these objections are</p>	<p>1 But if the Plaintiffs' counsel just</p> <p>2 wants me to object, then I will do that. That's</p> <p>3 fine.</p> <p>4 JUSTICE GREENSPAN: I think you should put the</p> <p>5 basis as sort of -- as you explained it to me, I am</p> <p>6 sure you will do a beautiful job putting it on the</p> <p>7 record. But once you do that, unless there is an</p> <p>8 objection based on something different, that</p> <p>9 objection will, you know -- there can be an</p> <p>10 agreement that just placing the objection will</p> <p>11 preserve that as the basis.</p> <p>12 MR. THORNBURGH: Yeah, your Honor, and this is</p> <p>13 Dan Thornburgh.</p> <p>14 I've already agreed that all he has to</p> <p>15 do is object. He doesn't have to give a basis and</p> <p>16 it won't be a waiver of any objection later on. I</p> <p>17 have already agreed to that with the exception of</p> <p>18 leading, because I need to know, if I asked it</p> <p>19 improperly, I need to know that I need to go back</p> <p>20 and correct the answer.</p> <p>21 But all he's got to do is say</p> <p>22 "Objection." We can handle the basis for the</p> <p>23 objection later on so that it doesn't interrupt the</p> <p>24 flow of this deposition.</p>
Page 107	Page 109
<p>1 coming from. Plaintiffs' counsel reading sentences</p> <p>2 from a document.</p> <p>3 JUSTICE GREENSPAN: Why don't you -- Burt,</p> <p>4 Burt, why don't you just say, "I have a standing</p> <p>5 objection based on the following." Put it on the</p> <p>6 record and then, you know, as the deposition</p> <p>7 continues on, just make your -- you don't have</p> <p>8 to -- unless it's something very different like</p> <p>9 it's leading or something like that where you can</p> <p>10 say "Objection; leading," why don't you just say</p> <p>11 "Objection" and that objection will hold for your</p> <p>12 standing objection.</p> <p>13 MR. SNELL: If --</p> <p>14 JUSTICE GREENSPAN: Do you understand what I'm</p> <p>15 saying?</p> <p>16 MR. SNELL: I think I do, your Honor. If</p> <p>17 that's the agreement, and there is absolutely --</p> <p>18 and I don't want to hear any argument of waiver</p> <p>19 because, your Honor, my big concern is they are</p> <p>20 going to try to say there is some waiver because I</p> <p>21 made these types of objections, your Honor, if you</p> <p>22 will recall, in his TVT de bene esse deposition</p> <p>23 when Mr. Freese was examining him because there are</p> <p>24 several things I think are improper.</p>	<p>1 JUSTICE GREENSPAN: Okay. Is that okay, Burt?</p> <p>2 Can we agree there?</p> <p>3 MR. SNELL: Yeah, yes, I guess we can, your</p> <p>4 Honor. I just really have a real concern about</p> <p>5 waiver issues.</p> <p>6 MR. THORNBURGH: I am telling you.</p> <p>7 JUSTICE GREENSPAN: Okay. You may have a</p> <p>8 valid, very valid basis to object. But, you know,</p> <p>9 as long as you state it on the record and, you</p> <p>10 know, it's going to be preserved.</p> <p>11 MR. SNELL: Okay.</p> <p>12 JUSTICE GREENSPAN: Just state that "When I</p> <p>13 say an objection, it's going to be -- that will be</p> <p>14 the basis unless I say otherwise, you know, unless</p> <p>15 there is some other basis, in which case I will</p> <p>16 make that clear."</p> <p>17 MR. SNELL: Okay. I think --</p> <p>18 JUSTICE GREENSPAN: How about that?</p> <p>19 MR. SNELL: I think I am understanding your</p> <p>20 Honor.</p> <p>21 MR. THORNBURGH: I think you're saying here</p> <p>22 are the objections I may have -- I have, I may have</p> <p>23 throughout the deposition, reading of documents,</p> <p>24 improper expert opinion testimony.</p>

Bruce Alan Rosenzweig, M.D.

Page 110	Page 112
<p>1 I think the best way to handle this is</p> <p>2 he can just object without giving a basis with the</p> <p>3 exception of leading, and it's not -- won't be a</p> <p>4 waiver of his objection if he doesn't give a basis.</p> <p>5 MR. BRADFORD: Of any basis.</p> <p>6 JUSTICE GREENSPAN: That's generally --</p> <p>7 generally that's true unless a basis is requested,</p> <p>8 unless the judge, and usually it's in the trial,</p> <p>9 the judge asks for a basis.</p> <p>10 MR. SNELL: That's what I am doing, your</p> <p>11 Honor, because this is a trial deposition just like</p> <p>12 Dr. Rosenzweig is before a jury. So, that was --</p> <p>13 that's my heightened sense. Obviously if it was a</p> <p>14 discovery depo, that's different.</p> <p>15 And your Honor has seen the types of</p> <p>16 objections I made in his first trial de bene esse</p> <p>17 deposition. They are like this: Objection;</p> <p>18 improper subject matter of an expert, you know,</p> <p>19 lacks facts or bases, state of mind. That's what</p> <p>20 I'm doing.</p> <p>21 MR. THORNBURGH: The difference here than a</p> <p>22 trial deposition is obviously we don't have a judge</p> <p>23 here, but what I'm -- what we are going to have is</p> <p>24 we are going to have arguments in front of probably</p>	<p>1 including violating PA procedure, with the</p> <p>2 exception of leading. I'll tell Mr. Thornburgh if</p> <p>3 it's actually leading as the basis. That's the</p> <p>4 agreement I guess.</p> <p>5 MR. THORNBURGH: Yes.</p> <p>6 MR. SNELL: Okay.</p> <p>7 JUSTICE GREENSPAN: Okay. Is that the</p> <p>8 agreement? Okay.</p> <p>9 MR. THORNBURGH: Yes.</p> <p>10 JUSTICE GREENSPAN: Make sure that goes on the</p> <p>11 record.</p> <p>12 MR. THORNBURGH: It is. And thank you so</p> <p>13 much. Thank you so much, your Honor. Appreciate</p> <p>14 it.</p> <p>15 MR. SNELL: Agreed. Thank you for your</p> <p>16 guidance.</p> <p>17 JUSTICE GREENSPAN: Okay. That's fine. Okay.</p> <p>18 MR. SNELL: Have a great day.</p> <p>19 JUSTICE GREENSPAN: Very good. Thank you.</p> <p>20 MR. SNELL: Bye.</p> <p>21 JUSTICE GREENSPAN: Bye.</p> <p>22 (WHEREUPON, the conference call with</p> <p>23 Justice Greenspan was concluded.)</p> <p>24</p>
Page 111	Page 113
<p>1 your Honor or before the trial judge on this, you</p> <p>2 know, the admissibility of these questions and</p> <p>3 answers and what I'm saying is he is not going to</p> <p>4 waive an objection if he doesn't give a basis.</p> <p>5 That will be taken up in front of your</p> <p>6 Honor or in front of the Trial Court prior to the</p> <p>7 trial. The problem with the way it's going on</p> <p>8 right now is it's interrupting the flow of the</p> <p>9 questions and answers.</p> <p>10 JUSTICE GREENSPAN: Okay. Well, let's try to</p> <p>11 get through it so that the interruptions are, you</p> <p>12 know, as minimal as possible.</p> <p>13 MR. SNELL: Okay.</p> <p>14 JUSTICE GREENSPAN: And we should -- that</p> <p>15 should work hopefully. I will keep my fingers</p> <p>16 crossed. Okay.</p> <p>17 MR. SNELL: Thank you for your guidance, your</p> <p>18 Honor. So I will just object.</p> <p>19 JUSTICE GREENSPAN: Thank you.</p> <p>20 MR. SNELL: Unless it's to leading and then I</p> <p>21 will say --</p> <p>22 JUSTICE GREENSPAN: I'm sorry?</p> <p>23 MR. SNELL: I will just object and it will</p> <p>24 preserve all my objections, whatever it is,</p>	<p>1 (WHEREUPON, the following further</p> <p>2 proceedings were had off the video</p> <p>3 record:)</p> <p>4 MR. SNELL: If it's leading, I got to tell you</p> <p>5 leading. Otherwise I just object.</p> <p>6 MR. BRADFORD: Leading, you know, if</p> <p>7 there's --</p> <p>8 MR. SNELL: No, no, no. Don't come in here --</p> <p>9 no, Brad.</p> <p>10 MR. BRADFORD: To the form of the question,</p> <p>11 leading, compound. If there is a form problem with</p> <p>12 the question that can be fixed, that's different</p> <p>13 than a substantive objection. Leading, compound,</p> <p>14 something like that that can be fixed.</p> <p>15 MR. SNELL: "Something like that." This is</p> <p>16 the slippery slope, "something like that," Brad.</p> <p>17 MR. THORNBURGH: No, listen, what he is saying</p> <p>18 is if your objection is to something that I can fix</p> <p>19 like --</p> <p>20 MR. SNELL: You can fix a lot, all this stuff.</p> <p>21 You can fix a lot of it.</p> <p>22 MR. THORNBURGH: No.</p> <p>23 MR. SNELL: I thought our agreement was as to</p> <p>24 leading. Otherwise I just say "Objection." Now we</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 114</p> <p>1 are changing? I'm not changing that.</p> <p>2 MR. THORNBURGH: It's okay. Just -- it's to</p> <p>3 leading. I don't care.</p> <p>4 I don't ask compound questions.</p> <p>5 (WHEREUPON, the deponent entered the</p> <p>6 proceedings.)</p> <p>7 (WHEREUPON, the following</p> <p>8 proceedings were had on the video</p> <p>9 record:)</p> <p>10 THE VIDEOGRAPHER: The time is 11:20 a.m. and</p> <p>11 we're back on the video record.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Doctor, before we went off the record,</p> <p>14 we were discussing Exhibit P1527 and we were on</p> <p>15 page 4 of the document that was attached, the</p> <p>16 charter agreement, Bates number ending in 857.</p> <p>17 Okay?</p> <p>18 A. Yes.</p> <p>19 Q. Are you there? And we were discussing</p> <p>20 the "Critical Assumptions" section, is that</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And what does the critical --</p> <p>24 what does that sentence under "Critical</p>	<p style="text-align: right;">Page 116</p> <p>1 shorter mesh was not found to have equivalent</p> <p>2 efficacy, that would lead to a no-go decision.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Equivalent efficacy to what products?</p> <p>5 A. The full-length TVT and TVT-O products.</p> <p>6 Q. Okay. In layman -- in layperson terms,</p> <p>7 what does it mean to -- what does "equivalent</p> <p>8 efficacy" mean?</p> <p>9 A. If -- that means that it works to treat</p> <p>10 the condition, which is incontinence, to about the</p> <p>11 same level.</p> <p>12 Q. Okay. So, if -- if it was determined</p> <p>13 before they launched the product that the TVT-Secur</p> <p>14 did not work as well as the TVT Retropubic or the</p> <p>15 TVT-Obturator, the TVT-O, what is your</p> <p>16 understanding as to what this no-go decision would</p> <p>17 require?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. That they not launch the product.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And is that an appropriate decision to</p> <p>23 make under such circumstances?</p> <p>24 MR. SNELL: Object.</p>
<p style="text-align: right;">Page 115</p> <p>1 Assumptions" say?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. "What are the assumptions about the</p> <p>5 project, which if incorrect, could result in a</p> <p>6 no-go decision?"</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And what is the first bullet point that</p> <p>9 was a critical assumption that if incorrect would</p> <p>10 result in a no-go decision?</p> <p>11 A. "Shorter" --</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. "Shorter mesh implanted will provide</p> <p>15 equivalent efficacy compared to current mesh length</p> <p>16 and position in both the retropubic and obturator</p> <p>17 direction."</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what's your understanding of that --</p> <p>20 that assumption that if incorrect would result in a</p> <p>21 no-go decision?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. That if the equivalency -- if the</p>	<p style="text-align: right;">Page 117</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And do you know whether or not, and</p> <p>5 we'll talk about it in greater detail, do you know</p> <p>6 whether or not Ethicon ever determined before they</p> <p>7 launched the TVT-Secur product that the TVT-Secur</p> <p>8 was less effective than the other devices that they</p> <p>9 had in their playground such as the TVT Retropubic</p> <p>10 and the TVT-Obturator?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And what was their -- what was the</p> <p>16 finding?</p> <p>17 A. That it was less effective.</p> <p>18 Q. And, so, based on this critical</p> <p>19 assumption, what could Ethicon have done when they</p> <p>20 determined that?</p> <p>21 A. Not launch the product.</p> <p>22 Q. And do you have an opinion whether or</p> <p>23 not Ethicon should or should not have launched the</p> <p>24 TVT-Secur product after they determined that it</p>

30 (Pages 114 to 117)

Bruce Alan Rosenzweig, M.D.

Page 118	Page 120
<p>1 lacked equivalent efficacy to the TVT Retropubic or</p> <p>2 TVT-Obturator products?</p> <p>3 A. Yes, I have an opinion.</p> <p>4 Q. What's that opinion?</p> <p>5 A. That they should not have launched it.</p> <p>6 Q. If we turn to the page ending in</p> <p>7 ETH.MESH.07898861 of Exhibit P1527, could you tell</p> <p>8 us what part of this page is important to your</p> <p>9 opinions?</p> <p>10 MR. SNELL: Object; leading.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. What's the next page that you'd like to</p> <p>13 discuss with the ladies and gentlemen of the jury?</p> <p>14 A. The -- it's marked as page 8 in the</p> <p>15 document.</p> <p>16 Q. And what's the significance of this</p> <p>17 page with respect to your opinions in this case?</p> <p>18 A. There is a discussion about how the</p> <p>19 TVT X, which ultimately became the TVT-Secur, would</p> <p>20 prevent the erosion of the pricing of the current</p> <p>21 slings and would help prevent loss of market share,</p> <p>22 but that some of the current users of their</p> <p>23 products would then switch to using the TVT-Secur.</p> <p>24 Q. Okay. And if we -- is there any other</p>	<p>1 laser-cut, rigid mesh, the sharp arrow tip</p> <p>2 introducer and the fleece tips that would hold the</p> <p>3 sling in place to treat stress urinary</p> <p>4 incontinence, those had never been used before but</p> <p>5 they are going to claim that it is similar to the</p> <p>6 products that had already been on the market.</p> <p>7 Q. And is it appropriate for a company to</p> <p>8 make claims that are unproven?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Why is that?</p> <p>14 Let me ask a better question.</p> <p>15 Do you have an opinion whether or not it</p> <p>16 is appropriate for a medical device company to make</p> <p>17 claims about their products that are not proven?</p> <p>18 MR. SNELL: Same objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I do have an opinion.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What's that opinion?</p> <p>23 A. It is not appropriate.</p> <p>24 Q. Why not?</p>
Page 119	Page 121
<p>1 section on this page that you'd like to discuss</p> <p>2 with the jury?</p> <p>3 A. Yes.</p> <p>4 Q. And what's that?</p> <p>5 A. That they are going to state that the</p> <p>6 product characteristics or claims about the product</p> <p>7 will be similar to the current TVT products.</p> <p>8 Q. And if we just pull up that paragraph</p> <p>9 that you're at. Are you at the second-to-last</p> <p>10 bolded section on this page?</p> <p>11 A. The last bolded section, "What claims</p> <p>12 will we make for the proposed solution?"</p> <p>13 Q. Okay. And it says, "Product claims will</p> <p>14 be similar to our classic TVT products, but we will</p> <p>15 add additional claims of being less invasive, which</p> <p>16 should not require a study to validate."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. And how is that important, if at all, to</p> <p>20 your opinions?</p> <p>21 A. Well, they're going to state that the</p> <p>22 product characteristics of this new product that</p> <p>23 had never been used before, never been tested, have</p> <p>24 device characteristics such as the short, stiff,</p>	<p>1 A. Because one should make claims about a</p> <p>2 product that is based on -- on evidence derived</p> <p>3 from clinical testing.</p> <p>4 Q. Do you have an opinion about whether or</p> <p>5 not Ethicon or at least Ethicon's employees had an</p> <p>6 understanding that the TVT-Secur was different, a</p> <p>7 different device than the TVT Retropubic or the</p> <p>8 TVT-Obturator?</p> <p>9 MR. SNELL: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And what's that opinion?</p> <p>14 A. That they knew it was a different</p> <p>15 device.</p> <p>16 Q. And what's the basis for that opinion?</p> <p>17 A. Internal documents and deposition</p> <p>18 testimony.</p> <p>19 Q. And will we discuss some of those</p> <p>20 documents today?</p> <p>21 A. Yes.</p> <p>22 Q. What's the next page that you'd like to</p> <p>23 discuss in this exhibit?</p> <p>24 A. Page 15.</p>

Bruce Alan Rosenzweig, M.D.

Page 122	Page 124
<p>1 Q. Is that ETH.MESH ending in 868 of</p> <p>2 Exhibit P1527?</p> <p>3 A. That is correct.</p> <p>4 Q. And what section or what section of this</p> <p>5 page do you want to discuss?</p> <p>6 A. It's called "Risk Assessment." It is</p> <p>7 the "Assumptions to Achieve Commitment," commitment</p> <p>8 meaning the commitment to proceed with the -- with</p> <p>9 the project.</p> <p>10 Q. Okay. And how is or what is significant</p> <p>11 on this page with respect to the opinions you are</p> <p>12 offering?</p> <p>13 MR. SNELL: Object. Go ahead.</p> <p>14 BY THE WITNESS:</p> <p>15 A. That one of the assumptions is that</p> <p>16 there will be no significant design changes at the</p> <p>17 start of a study that is being planned to be done</p> <p>18 before the device is marketed.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Okay. And -- and what's the next bullet</p> <p>21 point you'd like to discuss, if any?</p> <p>22 A. That the timeline assumes that there</p> <p>23 will be no design changes and the start of the</p> <p>24 study assumes that there will be no design changes</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Let me ask a better way.</p> <p>5 If Ethicon, based on your review of the</p> <p>6 documents, including this document in particular,</p> <p>7 if Ethicon had performed a pre-market study, in</p> <p>8 other words, a study before they launched the</p> <p>9 TVT-Secur, that determined that there were issues</p> <p>10 with the device in terms of its design</p> <p>11 characteristics, what would occur?</p> <p>12 A. Those --</p> <p>13 MR. SNELL: Same objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Those design characteristics should be</p> <p>16 changed to make the device either safer or more</p> <p>17 effective.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what would -- how would that impact,</p> <p>20 if at all, the -- Ethicon's timeline for launching</p> <p>21 the product?</p> <p>22 A. It would make the timeline longer. The</p> <p>23 current timeline assumes that they -- that the</p> <p>24 pre-market study will find neither an effectiveness</p>
Page 123	Page 125
<p>1 in the characteristics of the device, that the</p> <p>2 design is frozen meaning that there will be no</p> <p>3 changes made to the device.</p> <p>4 Q. All right. Let me -- let's look at the</p> <p>5 second bullet point. It says, "Timeline assumes</p> <p>6 results of the pre-market study does not require</p> <p>7 design changes."</p> <p>8 What does that mean? What's your</p> <p>9 understanding of that? How is that specific bullet</p> <p>10 point significant to your opinions?</p> <p>11 A. It's significant that this assumes that</p> <p>12 a study that is done in live women prior to the</p> <p>13 device being put on the market will not require any</p> <p>14 changes in the design characteristics of the</p> <p>15 device.</p> <p>16 Q. Okay. In other words, are you telling</p> <p>17 the ladies and gentlemen of the jury that if a</p> <p>18 pre-market study had found that there were problems</p> <p>19 with the design of the device, does this -- would</p> <p>20 this have required the company to go back and fix</p> <p>21 those design issues before they launched the</p> <p>22 product?</p> <p>23 MR. SNELL: Objection, including leading on</p> <p>24 that one.</p>	<p>1 issue or a safety issue that would require changes</p> <p>2 in the design characteristics.</p> <p>3 Q. And we had looked at a number of</p> <p>4 sections of this document, including a section that</p> <p>5 had discussed Ethicon's desire to become first to</p> <p>6 market, the mini-sling. Do you recall that --</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. -- testimony?</p> <p>10 MR. SNELL: Objection including leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And how could this -- how could a</p> <p>15 negative result in the pre-market studies that</p> <p>16 would require a design change of the TVT-Secur, how</p> <p>17 could that impact Ethicon's desire, if at all, to</p> <p>18 become first to market?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. If a design change was found to be</p> <p>22 warranted, that would prolong the timeline and</p> <p>23 would more likely make being first to market</p> <p>24 impossible.</p>

32 (Pages 122 to 125)

Bruce Alan Rosenzweig, M.D.

Page 126	Page 128
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And how would that -- a negative finding</p> <p>3 in their pre-market study that required a design</p> <p>4 change, how would that negative result and design</p> <p>5 change potentially impact Ethicon's market share?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Based on your review of these documents?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. It would negatively impact their market</p> <p>12 share as being first to market and is important to</p> <p>13 establish a market share.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Okay. Would Ethicon, based on your</p> <p>16 review of this document or these documents, lose</p> <p>17 money if -- if the pre-market study resulted in a</p> <p>18 negative finding that required a design change that</p> <p>19 resulted in a delay of launching the product which</p> <p>20 resulted in a competitor bringing their product to</p> <p>21 the market first?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes, they would lose money.</p>	<p>1 What's your understanding of that</p> <p>2 critical assumption and how does that, if at all,</p> <p>3 support your opinions?</p> <p>4 A. Well, that -- this document shows that</p> <p>5 or this document describes that as of December of</p> <p>6 2004 it was a new discovery that they would need to</p> <p>7 do a clinical trial prior to the launch of the</p> <p>8 product.</p> <p>9 Q. And it says, "Pre-Market study outcomes</p> <p>10 that drive design changes."</p> <p>11 Did I read that correctly?</p> <p>12 A. Yes.</p> <p>13 Q. And how, if at all, does that critical</p> <p>14 assumption support your opinions?</p> <p>15 A. Well, this supports my opinions that a</p> <p>16 pre-market study is important to test the safety</p> <p>17 and efficacy of a product and in -- and,</p> <p>18 particularly, the design characteristics of that</p> <p>19 product that would make it either less effective or</p> <p>20 less safe and that a pre-market study that</p> <p>21 determines if there are design characteristics that</p> <p>22 make it unsafe or less effective would then drive</p> <p>23 changes in those design characteristics to make it</p> <p>24 more effective and more safe.</p>
Page 127	Page 129
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Is there any other section or page of</p> <p>3 this exhibit that you'd like to discuss?</p> <p>4 A. It is page 17 or ETH.MESH ending in</p> <p>5 8870.</p> <p>6 Q. Okay. And what is significant on this</p> <p>7 page of Exhibit P1527?</p> <p>8 A. It describes critical assumptions that</p> <p>9 are fundamental for the project to be successful</p> <p>10 but outside the control of the team that is</p> <p>11 responsible for the design, development and testing</p> <p>12 of the device characteristics.</p> <p>13 Q. And what section are you speaking about</p> <p>14 on this page?</p> <p>15 A. It is under "Critical Assumptions."</p> <p>16 Q. And it says, "Critical Assumptions.</p> <p>17 Identify critical assumptions fundamental to</p> <p>18 success but outside the control of the team."</p> <p>19 And there is a list of those critical</p> <p>20 assumptions, is that correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And No. 2 says, "New discoveries</p> <p>23 drive the need for a clinical trial prior to</p> <p>24 launch."</p>	<p>1 Q. And is -- let me ask you this question:</p> <p>2 Do you have an opinion whether or not companies who</p> <p>3 should perform adequate testing -- strike that.</p> <p>4 Do you have an opinion whether or not</p> <p>5 Ethicon should have performed adequate pre-market</p> <p>6 studies before launching the TVT-Secur product?</p> <p>7 A. Yes, I have an opinion.</p> <p>8 Q. What's that opinion?</p> <p>9 A. They should have performed testing.</p> <p>10 Q. And if Ethicon had performed pre-market</p> <p>11 human studies and found that the product lacked</p> <p>12 efficacy or had safety issues, do you have an</p> <p>13 opinion what Ethicon should have done?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes, either not launched the product or</p> <p>17 defined what are those design characteristics that</p> <p>18 either are leading to less efficacy or less -- or</p> <p>19 impaired safety and changed those design</p> <p>20 characteristics to improve efficacy and improve</p> <p>21 safety.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And why, if at all, is that important?</p> <p>24 A. It's important because that impacts</p>

33 (Pages 126 to 129)

Bruce Alan Rosenzweig, M.D.

Page 130	Page 132
<p>1 patient safety.</p> <p>2 Q. What do you mean it "impacts patient</p> <p>3 safety"?</p> <p>4 A. Well, if it -- if there are</p> <p>5 characteristics of the device that are unreasonably</p> <p>6 unsafe, then the patient is exposed to design</p> <p>7 characteristics that are unreasonably unsafe. It</p> <p>8 leads to complications.</p> <p>9 A less effective device means that the</p> <p>10 patient is not treated for stress urinary</p> <p>11 incontinence and then would require additional</p> <p>12 treatment or additional surgery to treat their</p> <p>13 remaining or recurrent stress urinary incontinence.</p> <p>14 Q. What's the next exhibit that you'd like</p> <p>15 to discuss?</p> <p>16 A. It is marked P0732. It is an e-mail</p> <p>17 between Ethicon employees, including Dan Smith,</p> <p>18 lead engineer and patent holder, one of the patent</p> <p>19 holders for the TVT-Secur. It's from December 14,</p> <p>20 2004, and it is describing the comparison between</p> <p>21 laser-cut mesh and mechanical-cut mesh.</p> <p>22 Q. Okay. And how does this Exhibit 732</p> <p>23 support your opinions, if at all?</p> <p>24 A. It supports my opinions that laser-cut</p>	<p>1 pain with intercourse.</p> <p>2 Q. What's the basis for that opinion,</p> <p>3 Doctor?</p> <p>4 A. The medical literature.</p> <p>5 Q. And will we -- will we review some of</p> <p>6 those medical literature today?</p> <p>7 MR. SNELL: Objection; leading.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Let me say it a better way. We'll</p> <p>10 discuss some of those later on.</p> <p>11 Is it fair to say that we will discuss</p> <p>12 some of those supporting --</p> <p>13 A. That is --</p> <p>14 Q. -- medical literature later today?</p> <p>15 MR. SNELL: Objection; leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. That has been described in my prior</p> <p>18 testimony, yes.</p> <p>19 I'd also like to point out that this</p> <p>20 document also found that at one inch of stress,</p> <p>21 laser-cut mesh was three times stiffer than</p> <p>22 mechanical-cut mesh.</p> <p>23 However, attached to this document is a</p> <p>24 comparison with other competitors which showed that</p>
Page 131	Page 133
<p>1 mesh is three times stiffer than mechanical-cut</p> <p>2 mesh, making the short TVT-Secur stiffer than the</p> <p>3 full-length TVT devices that were on the market in</p> <p>4 2004 through the time of launch in 2006.</p> <p>5 Q. Does that matter?</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Do you have an opinion whether or not it</p> <p>9 matters that the TVT laser-cut mesh was more stiff</p> <p>10 than laser-cut mesh?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Does that -- is there -- let me ask a</p> <p>14 better question.</p> <p>15 Do you have an opinion whether or not</p> <p>16 there is any clinical significance to a -- having a</p> <p>17 stiffer mesh device?</p> <p>18 A. Yes. A stiffer mesh device is a design</p> <p>19 characteristic that increases harm to women.</p> <p>20 Stiffness of the mesh increases the chronic</p> <p>21 inflammation, chronic foreign body reaction, the</p> <p>22 degree of scar-plating that occurs which results in</p> <p>23 the injuries, mesh erosion, mesh contraction, which</p> <p>24 can obstruct the urethra, and can lead to pain and</p>	<p>1 laser-cut mesh was less stiff and establishing a</p> <p>2 lower resistance load to competitor mesh.</p> <p>3 Q. Okay. And is that important at all in</p> <p>4 your opinions?</p> <p>5 A. Yes. Those other slings are -- have</p> <p>6 design characteristics that make them unreasonably</p> <p>7 unsafe.</p> <p>8 Q. So, do you have an opinion whether or</p> <p>9 not because of the mesh characteristics or the</p> <p>10 stiffness of the TVT laser-cut mesh, whether or not</p> <p>11 those characteristics make the TVT laser-cut</p> <p>12 devices unreasonably unsafe as well?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 MR. SNELL: Go ahead.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What's that opinion?</p> <p>19 A. That it -- the laser cutting makes the</p> <p>20 TVT-Secur, the short TVT-Secur mesh unreasonably</p> <p>21 unsafe due to the stiffness and rigidity associated</p> <p>22 with the short mesh and compounded by the laser</p> <p>23 cutting of the short mesh.</p> <p>24 Q. What's the next exhibit that you'd like</p>

34 (Pages 130 to 133)

Bruce Alan Rosenzweig, M.D.

Page 134	Page 136
<p>1 to discuss with the ladies and gentlemen of the</p> <p>2 jury?</p> <p>3 A. It's ETH.MESH ending in 9108.</p> <p>4 Q. Is there a P number, an Exhibit number?</p> <p>5 A. P1318.</p> <p>6 MR. SNELL: While you are looking, I'm just</p> <p>7 going to object on P1527. That was not on the</p> <p>8 doctor's reliance list. So, I move to strike any</p> <p>9 and all testimony about that exhibit.</p> <p>10 MR. THORNBURGH: Hold on a second. P what?</p> <p>11 The last exhibit? I'm sorry. P1318?</p> <p>12 MR. SNELL: P1527.</p> <p>13 MR. THORNBURGH: 1527. What is that one? The</p> <p>14 charter agreement?</p> <p>15 MR. SNELL: Yes.</p> <p>16 MR. THORNBURGH: He's testified about the</p> <p>17 charter agreement in multiple trials. I think it's</p> <p>18 on his reliance list, as well as the deposition</p> <p>19 testimony of people who have testified about that</p> <p>20 document like Renee Selman and he disclosed all</p> <p>21 exhibits with respect to those witnesses that were</p> <p>22 on -- attached to those transcripts as you guys</p> <p>23 know.</p> <p>24 So, we can resolve that issue.</p>	<p>1 product is designed, developed and tested and the</p> <p>2 steps taken to validate the design and development</p> <p>3 and testing of the product.</p> <p>4 Q. And have you reviewed the TVT</p> <p>5 internal -- strike that.</p> <p>6 Have you reviewed the internal Ethicon</p> <p>7 company documents concerning the design validation</p> <p>8 of the TVT-Secur?</p> <p>9 A. Correct.</p> <p>10 Q. And is this one of those documents?</p> <p>11 A. Yes.</p> <p>12 Q. And what part of this e-mail string do</p> <p>13 you want to discuss that support your opinions?</p> <p>14 A. Well, this document is discussing one of</p> <p>15 the design processes, which is the -- included a</p> <p>16 cadaver or series of cadaver labs where doctors and</p> <p>17 surgeons were invited to come and place the device</p> <p>18 in cadavers.</p> <p>19 And there was a degree of difficulty,</p> <p>20 which is described in the beginning of the e-mail</p> <p>21 string, of -- that these doctors were having</p> <p>22 trouble with the introducers and passing the device</p> <p>23 in a certain -- in the appropriate place during</p> <p>24 these cadaver studies, which then led to one of the</p>
Page 135	Page 137
<p>1 MR. SNELL: It's okay. Mr. Thornburgh made</p> <p>2 his position clear.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. I'm sorry. Just back to where we were.</p> <p>5 What exhibit do you want to discuss with</p> <p>6 the ladies and gentlemen of the jury next?</p> <p>7 A. 1318.</p> <p>8 Q. And I'll hand defense counsel a copy of</p> <p>9 that exhibit.</p> <p>10 What is that exhibit? What is this</p> <p>11 document?</p> <p>12 A. It's an e-mail string between Gary</p> <p>13 Borkes, who is design quality engineer, and other</p> <p>14 key Ethicon employees, including Dan Smith, who is</p> <p>15 an engineer and lead engineer on the TVT-Secur</p> <p>16 project, Mark Weisberg, Allison London Brown, who</p> <p>17 is the worldwide project leader for the TVT-Secur,</p> <p>18 discussing the design validation process.</p> <p>19 Q. Okay. So, let me just try to understand</p> <p>20 some things and orient the jury a little bit as</p> <p>21 well.</p> <p>22 What is a -- it says, "Des Val." What</p> <p>23 is design validation?</p> <p>24 A. It is the process by which a medical</p>	<p>1 people observing this, Dan Smith, coming in and</p> <p>2 explained to them the way to do it.</p> <p>3 And what Gary Borkes is describing is</p> <p>4 that design validation is not just a box to check</p> <p>5 off or, as he describes in the e-mail, a hurdle to</p> <p>6 pass, but the way things should be done.</p> <p>7 It's important to get this right so that</p> <p>8 any characteristics of the device that make it</p> <p>9 unreasonably unsafe or unreasonably less effective</p> <p>10 can be discovered so that those characteristics can</p> <p>11 be changed to make the device more effective and</p> <p>12 more safe.</p> <p>13 Q. Okay. So, let me break that down a</p> <p>14 little bit because that was a lot of information.</p> <p>15 You had indicated that design validation</p> <p>16 is a tool for understanding potential issues with a</p> <p>17 device or with the IFU?</p> <p>18 MR. SNELL: Object and leading.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What is the purpose of design</p> <p>21 validation?</p> <p>22 A. Well, to validate all of the</p> <p>23 characteristics of the device, which includes the</p> <p>24 device, would include the Instructions for Use, the</p>

Bruce Alan Rosenzweig, M.D.

Page 138	Page 140
<p>1 technique to implant the device, and the training</p> <p>2 on how to implant the device.</p> <p>3 Q. And at this point in time, in 2005, with</p> <p>4 respect to the design validation, what was Ethicon</p> <p>5 attempting to do?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. What, if anything, was Ethicon</p> <p>9 attempting to do?</p> <p>10 A. Well, this is describing cadaver labs</p> <p>11 that were being done. This is to see how doctors</p> <p>12 are able to use the device albeit in a dead body or</p> <p>13 a cadaver.</p> <p>14 Q. And are these -- is this design</p> <p>15 validation process an important process to the</p> <p>16 ultimate development and launch of products?</p> <p>17 A. Yes. This helps the design team</p> <p>18 discover characteristics of the device that either</p> <p>19 make it unreasonably unsafe or make it ineffective.</p> <p>20 Q. What, if anything, can happen to</p> <p>21 patients if design validation protocols aren't</p> <p>22 followed?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>	<p>1 unreasonably unsafe or if they impact the</p> <p>2 effectiveness of the device.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Now, I just want to have you orient this</p> <p>5 for the jury, ladies and gentlemen of the jury.</p> <p>6 If we look at ETH.MESH.05559109 of</p> <p>7 Exhibit 1318, there is a discussion that's</p> <p>8 occurring with Gary Borkes to a number of other</p> <p>9 Ethicon employees, is that correct?</p> <p>10 MR. SNELL: Object; leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And without having to run through all of</p> <p>15 this lengthy sort of -- these lengthy comments, the</p> <p>16 first bullet point says, "He commented that</p> <p>17 (somehow) he was shown how to attach the needle</p> <p>18 holder prior to starting the training; and if it</p> <p>19 wasn't for that, in his opinion the technique was</p> <p>20 not clearly defined via the draft IFU verbiage or</p> <p>21 the picture."</p> <p>22 Did I read that correctly?</p> <p>23 MR. SNELL: Object and leading.</p> <p>24 BY THE WITNESS:</p>
Page 139	Page 141
<p>1 A. A device that has device characteristics</p> <p>2 that make it unreasonably unsafe or make it</p> <p>3 ineffective in treating the condition that it is</p> <p>4 being used for, if the design validation process is</p> <p>5 not done completely, accurately and effectively,</p> <p>6 would mean that those characteristics get into a</p> <p>7 device and women are exposed to the design</p> <p>8 characteristics that make it unreasonably unsafe or</p> <p>9 less effective.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Do you have an opinion whether or not</p> <p>12 companies should take their time in performing</p> <p>13 design validation studies?</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What's that opinion?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That they should take their time and</p> <p>22 know -- both clinically test and test in the design</p> <p>23 validation process all the characteristics of a</p> <p>24 medical device to determine whether they are</p>	<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And do you have any opinions about that</p> <p>4 issue, in other words -- said, in other words --</p> <p>5 strike that.</p> <p>6 Do you have any opinions whether or not,</p> <p>7 with respect to this TVT-Secur design validation,</p> <p>8 it would have been appropriate for an Ethicon</p> <p>9 employee to show one of the physicians who were</p> <p>10 participating in this design validation how to</p> <p>11 perform the technique without letting the doctor</p> <p>12 try to figure out based on his or her review of the</p> <p>13 IFU how to do the procedure with only using the</p> <p>14 IFU?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. I do have an opinion.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what's that?</p> <p>20 A. That would not be appropriate.</p> <p>21 Q. And why is that?</p> <p>22 A. Because the Instructions for Use is the</p> <p>23 one document that the manufacturer knows that every</p> <p>24 physician has at the most crucial time of placing</p>

Bruce Alan Rosenzweig, M.D.

Page 142	Page 144
<p>1 the device, which is at the time that the device is</p> <p>2 being placed. The Instructions for Use should be</p> <p>3 able to describe how a device is implanted.</p> <p>4 If this doctor, who is described in this</p> <p>5 e-mail, could not clearly -- if the technique could</p> <p>6 not be clearly defined via the draft of the IFU</p> <p>7 verbiage, then that shows that the IFU verbiage has</p> <p>8 characteristics of it that make it unreasonably</p> <p>9 unsafe or defective.</p> <p>10 Q. In this first bullet point what was</p> <p>11 being recommended?</p> <p>12 A. That there might be or there would be</p> <p>13 benefit for making the steps that are described in</p> <p>14 the procedural steps more clear and accurate so</p> <p>15 that a doctor would be able to use the Instructions</p> <p>16 for Use in a safe and effective way to implant the</p> <p>17 device in women.</p> <p>18 Q. Okay. And does Dan Smith respond to the</p> <p>19 comments that Gary Borkes shared?</p> <p>20 A. Yes.</p> <p>21 Q. And what was Dan Smith's response?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Basically he states that "I am through</p>	<p>1 but I am through making non-value added changes to</p> <p>2 a document that is 1,000 times more accurate and</p> <p>3 complete than TVT."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 MR. SNELL: Objection and leading.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Dan Smith goes on and says or writes, "I</p> <p>9 have drawn the line, unless someone can demonstrate</p> <p>10 a 'real' deficiency in the document. This is a</p> <p>11 waste of time and it is holding up the project in</p> <p>12 many ways."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object and leading.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And is it appropriate for Dan Smith, the</p> <p>19 inventor or co-inventor of the TVT-Secur device,</p> <p>20 who is a non-doctor, to be pushing back on whether</p> <p>21 or not the IFU should be changed to make it more</p> <p>22 accurate so that physicians can safely implant the</p> <p>23 TVT-Secur device?</p> <p>24 MR. SNELL: Object.</p>
Page 143	Page 145
<p>1 making non-value added changes to a document," and</p> <p>2 that document is the Instructions for Use.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Dan Smith a doctor or not doctor?</p> <p>5 MR. SNELL: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. He is not a doctor.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Is it appropriate, in your opinion, for</p> <p>10 Ethicon to allow non-doctors to make decisions</p> <p>11 about information that should be shared with</p> <p>12 doctors?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. About the proper implantation technique</p> <p>16 for the TVT-Secur device?</p> <p>17 MR. SNELL: Same objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. That should be the Medical Affairs</p> <p>20 purview.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And, so, if we look at 1318, the first</p> <p>23 page, Dan Smith writes, "Gary, please find my</p> <p>24 comments below and do not take this the wrong way,</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes, I have an opinion.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What's that opinion?</p> <p>5 A. No, it is not appropriate.</p> <p>6 Q. And Gary Borkes responds. Do you see</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. And Gary Borkes is -- who is Gary</p> <p>10 Borkes? Is he another employee of Ethicon?</p> <p>11 A. He is a design quality engineer.</p> <p>12 Q. Okay. And Gary Borkes responds and</p> <p>13 says, "Please don't take this the wrong way...but</p> <p>14 why do you think we are doing design validation</p> <p>15 exercises?"</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 MR. SNELL: Objection and leading.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. He goes on and writes, "It is not just</p> <p>21 another hurdle to 'pass,' although I get the</p> <p>22 impression that some might feel that way."</p> <p>23 Did I read that correctly?</p> <p>24 MR. SNELL: Objection and leading.</p>

Bruce Alan Rosenzweig, M.D.

Page 146	Page 148
<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Do you agree with Gary Borkes?</p> <p>5 A. Yes.</p> <p>6 Q. He writes, goes on and writes towards</p> <p>7 the end of this second paragraph, "I believe the</p> <p>8 timeline pressures are recognized and felt by</p> <p>9 everyone - believe me, Dan, the overwhelming load</p> <p>10 (even me - how about that). But we also have to</p> <p>11 properly evaluate user input, or it could bite the</p> <p>12 product down the road."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object and leading.</p> <p>15 BY THE WITNESS:</p> <p>16 A. You missed one line that says, "Everyone</p> <p>17 I talk to says how under the gun they are and how</p> <p>18 much they are trying to push to support you and the</p> <p>19 project despite the overwhelming load."</p> <p>20 But beside that, yes, you read that</p> <p>21 correctly.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And do you have any opinions about this</p> <p>24 response by Gary Borkes?</p>	<p>1 Q. What's that opinion?</p> <p>2 A. They did not.</p> <p>3 Q. And do you have an opinion whether or</p> <p>4 not Ethicon's failure to properly perform the</p> <p>5 TVT-Secur design validation ended up as, using Gary</p> <p>6 Borkes' words, biting the product down the road?</p> <p>7 MR. SNELL: Object and leading.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I do have an opinion.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And what's that?</p> <p>12 MR. SNELL: Same.</p> <p>13 BY THE WITNESS:</p> <p>14 A. That that is a correct statement by Gary</p> <p>15 Borkes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And we will get into this in more --</p> <p>18 more detail later on.</p> <p>19 But do you have an opinion whether or</p> <p>20 not the TVT-Secur ultimately was a failed product?</p> <p>21 A. Yes, I do have an opinion.</p> <p>22 Q. And what's that opinion?</p> <p>23 A. That it was a failed product.</p> <p>24 Q. And what's the basis for that opinion?</p>
Page 147	Page 149
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes, I do have an opinion.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What's the opinion?</p> <p>6 MR. SNELL: Same.</p> <p>7 BY THE WITNESS:</p> <p>8 A. That if the design validation process is</p> <p>9 not done in the appropriate manner, then</p> <p>10 characteristics of the device that make it</p> <p>11 unreasonably unsafe or make it unreasonably less</p> <p>12 effective will not be identified prior to the</p> <p>13 launch of the product and that women will be</p> <p>14 exposed to a device that has design characteristics</p> <p>15 that make it unreasonably unsafe or unreasonably</p> <p>16 ineffective.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Do you have an opinion whether or not</p> <p>19 Ethicon properly performed its design validation of</p> <p>20 the TVT-Secur device?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I do have an opinion.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 A. Internal Ethicon documents, particularly</p> <p>2 a document from Dan Smith, the inventor.</p> <p>3 Q. And ultimately did -- let me ask this</p> <p>4 question: Is the TVT-Secur still on the market?</p> <p>5 A. No, it is not.</p> <p>6 Q. And do you have an understanding as to</p> <p>7 why?</p> <p>8 A. It was removed from the market in 2012.</p> <p>9 Q. And do you have an understanding as to</p> <p>10 whether or not the safety or efficacy of the</p> <p>11 TVT-Secur product led to that determination?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Do you have an opinion based on your</p> <p>15 review of the internal documents and the medical</p> <p>16 literature?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes, I do.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What's that opinion? What's that</p> <p>22 opinion?</p> <p>23 A. That the inferior efficacy and the</p> <p>24 higher adverse event profile led to it being</p>

38 (Pages 146 to 149)

Bruce Alan Rosenzweig, M.D.

Page 150	Page 152
<p>1 removed -- was one of the issues that led to it</p> <p>2 being removed from the market.</p> <p>3 MR. THORNBURGH: Okay. Let's go ahead and</p> <p>4 take a break.</p> <p>5 THE VIDEOGRAPHER: Okay. The time is 12 noon</p> <p>6 and we're going off the video record.</p> <p>7 (WHEREUPON, the following</p> <p>8 proceedings were had off the video</p> <p>9 record:)</p> <p>10 MR. SNELL: Before we go off the steno record,</p> <p>11 I would note we have been unable to locate P1318 on</p> <p>12 the reliance list. I move to strike any and all</p> <p>13 testimony regarding P1318.</p> <p>14 MR. THORNBURGH: I will show you now or I will</p> <p>15 show you later. We can deal with it.</p> <p>16 MR. SNELL: I'm just saying Paul has checked</p> <p>17 and checked and checked. He doesn't have Borkes'</p> <p>18 depo. He doesn't have this document on his</p> <p>19 reliance list.</p> <p>20 MR. THORNBURGH: I don't want to show him</p> <p>21 Borkes' deposition. Borkes wasn't deposed.</p> <p>22 MR. SNELL: It's not on his reliance list as</p> <p>23 far as I can tell.</p> <p>24 MR. BRADFORD: He's making an objection.</p>	<p>1 A. Dr. Weisberg is a Senior Medical</p> <p>2 Director at Ethicon.</p> <p>3 Q. And what is the title of this document?</p> <p>4 A. It's the Clinical Expert Report for the</p> <p>5 TVT-Secur.</p> <p>6 Q. And you testified just a moment ago this</p> <p>7 was dated December 2, 2005?</p> <p>8 A. Correct.</p> <p>9 Q. And when was the TVT-Secur product</p> <p>10 launched?</p> <p>11 A. September --</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. September 20, 2006.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Okay. And was this document signed a</p> <p>17 little less than a year prior to the launch of the</p> <p>18 TVT-Secur product?</p> <p>19 A. Yes.</p> <p>20 Q. And you've testified previously about</p> <p>21 randomized controlled trials and what they are. Is</p> <p>22 that correct?</p> <p>23 A. Yes.</p> <p>24 Q. And I don't want to go into great</p>
Page 151	Page 153
<p>1 MR. SNELL: I'm just making an objection. No</p> <p>2 big deal.</p> <p>3 MR. THORNBURGH: That's fine.</p> <p>4 MR. SNELL: If I'm wrong, I'm wrong. I will</p> <p>5 freely say I'm wrong. But we checked and checked.</p> <p>6 I asked Paul to check four different ways.</p> <p>7 THE WITNESS: I will be a witness. Burt has</p> <p>8 said, "I was wrong."</p> <p>9 MR. SNELL: Yes, I will freely admit when I am</p> <p>10 totally wrong.</p> <p>11 (WHEREUPON, a recess was had</p> <p>12 from 12:00 to 1:07 p.m.)</p> <p>13 THE VIDEOGRAPHER: The time is 1:07 p.m. and</p> <p>14 we're back on the video record.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Good afternoon, Doctor.</p> <p>17 A. Good afternoon.</p> <p>18 Q. Dr. Rosenzweig, what's the next exhibit</p> <p>19 in your binder, which is I think we've marked as</p> <p>20 Exhibit No. 5, that you'd like to discuss?</p> <p>21 A. P number 1177. It's the Clinical Expert</p> <p>22 Report for the TVT-Secur device authored by</p> <p>23 Dr. Martin Weisberg and dated December 2, 2005.</p> <p>24 Q. And who is Dr. Weisberg?</p>	<p>1 detail, but what is a randomized controlled trial?</p> <p>2 A. Randomized controlled trials are high</p> <p>3 level evidence, some of the highest level of</p> <p>4 evidence in a single clinical study where a</p> <p>5 hypothesis is generated, a method of looking at</p> <p>6 that hypothesis is created, and patients are put in</p> <p>7 either one group getting treatment or another</p> <p>8 group, which is called the control group.</p> <p>9 They're randomly assigned, which should</p> <p>10 make the groups equal in their similarity as far as</p> <p>11 medical conditions, age, and the like, and then the</p> <p>12 data is collected and analyzed.</p> <p>13 Q. Did Ethicon -- do you know whether or</p> <p>14 not Ethicon had conducted a randomized controlled</p> <p>15 trial prior to launching or selling to patients or</p> <p>16 doctors the TVT-Secur device?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. They did not.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Let me ask that a better way since I got</p> <p>22 an objection.</p> <p>23 Do you know whether or not Ethicon</p> <p>24 deducted a randomized controlled trial prior to</p>

Bruce Alan Rosenzweig, M.D.

Page 154	Page 156
<p>1 launching the TVT-Secur product?</p> <p>2 A. They did not.</p> <p>3 Q. Do you know whether or not Ethicon had</p> <p>4 initially planned on conducting a randomized</p> <p>5 controlled trial before launching the TVT-Secur?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes, I saw documents that discussed</p> <p>9 conducting a randomized controlled trial.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And do you have an understanding as to</p> <p>12 the reason why Ethicon chose not to conduct a</p> <p>13 randomized controlled trial prior to launching the</p> <p>14 product?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what's that understanding?</p> <p>20 A. Due to budget constraints.</p> <p>21 Q. And what's the basis for that opinion,</p> <p>22 that testimony?</p> <p>23 A. Internal Ethicon documents.</p> <p>24 Q. And ultimately did Ethicon conduct any</p>	<p>1 No. from P1177 ending in 243, and just let me know</p> <p>2 when you're there.</p> <p>3 A. Yes.</p> <p>4 Q. What's the significance, if any, of this</p> <p>5 page from Exhibit P1177?</p> <p>6 A. Well, as of December 2, 2005,</p> <p>7 Dr. Weisberg concluded that additional clinical</p> <p>8 studies to support the safety and effectiveness are</p> <p>9 not necessary prior to releasing the product.</p> <p>10 Q. Did -- do you know whether or not</p> <p>11 Dr. Weisberg had signed off on the safety and</p> <p>12 efficacy of the TVT-Secur product prior to launch?</p> <p>13 A. Yes.</p> <p>14 Q. Is that what this document is?</p> <p>15 A. Yes.</p> <p>16 Q. How does this document support your</p> <p>17 opinions with respect to the clinical control</p> <p>18 studies or the First Human Use Study that we'll</p> <p>19 talk about later on that were done -- that was done</p> <p>20 by Ethicon in April, began in April of 2006?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Let me ask a better question.</p> <p>24 How does this document or this section</p>
Page 155	Page 157
<p>1 study in humans before they launched the TVT-Secur</p> <p>2 product?</p> <p>3 A. There was a study that was started, if I</p> <p>4 recall, in April of 2006 and prior to launch they</p> <p>5 had data, five-week data on 31 patients.</p> <p>6 Q. Okay. And, so, this document, dated</p> <p>7 December 2, 2005, was signed prior to the beginning</p> <p>8 of the clinical study that was done by Ethicon?</p> <p>9 A. Yes, based on my understanding.</p> <p>10 Q. Okay. And the clinical study that was</p> <p>11 done prior to launch, can you just briefly describe</p> <p>12 what kind of study that was, how many patients and</p> <p>13 the duration of the available data at launch?</p> <p>14 A. Well, it was a prospective study that</p> <p>15 was done at several centers and they had data on 31</p> <p>16 patients that had been treated with the TVT-Secur</p> <p>17 and had the TVT-Secur in them for five weeks.</p> <p>18 Q. Okay. And did you also read the</p> <p>19 testimony of Dr. Martin Weisberg?</p> <p>20 A. Yes.</p> <p>21 Q. And did you rely at least in part on the</p> <p>22 testimony of Dr. Martin Weisberg for your opinions?</p> <p>23 A. Yes.</p> <p>24 Q. And if you just turn with me to Bates</p>	<p>1 of the document support your opinions?</p> <p>2 A. As of December 2, 2005, Dr. Weisberg had</p> <p>3 already concluded -- Dr. Weisberg, the Medical</p> <p>4 Director at Ethicon, had already concluded that</p> <p>5 additional clinical studies were not necessary to</p> <p>6 determine safety and efficacy of the product prior</p> <p>7 to release.</p> <p>8 Q. Do you agree with that determination by</p> <p>9 Dr. Weisberg?</p> <p>10 A. No.</p> <p>11 Q. Did Dr. Weisberg sign off on the safety</p> <p>12 and efficacy of the TVT-Secur product before the</p> <p>13 clinical data had ever been analyzed?</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And I want to talk about this in greater</p> <p>19 detail later on, but the First Human Use Study or</p> <p>20 the first human study that Ethicon did, when was</p> <p>21 the interim data available to Ethicon?</p> <p>22 A. The interim data was looked at two weeks</p> <p>23 prior to launch.</p> <p>24 Q. And do you have an opinion whether or</p>

40 (Pages 154 to 157)

Bruce Alan Rosenzweig, M.D.

Page 158	Page 160
<p>1 not the first human clinical data interim analysis</p> <p>2 supported the safety and efficacy of the TVT-Secur</p> <p>3 product?</p> <p>4 A. Yes, I do have an opinion.</p> <p>5 Q. What's that opinion?</p> <p>6 A. It did not support the safety and</p> <p>7 efficacy of the TVT-Secur.</p> <p>8 Q. Do you have an opinion whether or not</p> <p>9 Ethicon should have conducted a randomized</p> <p>10 controlled trial before signing off on the safety</p> <p>11 and efficacy of the TVT-Secur product?</p> <p>12 A. Yes, I do have an opinion.</p> <p>13 Q. What's that opinion?</p> <p>14 A. They should have done a randomized</p> <p>15 controlled trial before signing off on the safety</p> <p>16 and efficacy of the product.</p> <p>17 Q. Do you have an opinion whether or not</p> <p>18 Ethicon should have at least waited for the</p> <p>19 five-week 31 patient interim data before signing</p> <p>20 off on the safety and efficacy of the Ethicon</p> <p>21 TVT-Secur product?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes, I do have an opinion.</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. What's that opinion?</p> <p>3 A. That it did not support the safety and</p> <p>4 efficacy of the TVT-Secur.</p> <p>5 Q. And why not?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. The failure rate was approximately 30%</p> <p>9 and the complication rate was approximately 60%.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Based on your review of Dr. Weisberg's</p> <p>12 Clinical Expert Report and the other interim -- and</p> <p>13 the other internal documents that we'll discuss</p> <p>14 today, do you have an opinion whether or not the</p> <p>15 clinical study that was done by Ethicon mattered to</p> <p>16 Dr. Weisberg or the Medical Affairs department in</p> <p>17 terms of determining whether the TVT-Secur product</p> <p>18 was safe and effective?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes, I do.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What's that opinion?</p> <p>24 A. That it did not seem to be important --</p>
Page 159	Page 161
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And what's that opinion?</p> <p>3 A. That the safety and efficacy -- the data</p> <p>4 from the five-week 31 patients should have been an</p> <p>5 important consideration to look at prior to signing</p> <p>6 off on the Clinical Expert Report and deeming that</p> <p>7 no further safety and efficacy data is necessary</p> <p>8 prior to launch.</p> <p>9 Q. And did the interim data from the First</p> <p>10 Human Use Study, was that available prior to</p> <p>11 launch?</p> <p>12 A. The interim data, yes.</p> <p>13 Q. When did that data become available?</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Again, it was looked at two weeks prior</p> <p>17 to launch.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And do you have an opinion whether or</p> <p>20 not the interim data supported the safety and</p> <p>21 efficacy of the TVT-Secur product?</p> <p>22 MR. SNELL: Object; repetition.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I do have an opinion.</p>	<p>1 that that data did not seem to be important in the</p> <p>2 decision whether or not to launch the product.</p> <p>3 Q. Other than the five-week 31 patient</p> <p>4 First Human Use interim data, what other studies</p> <p>5 did Ethicon do in humans, live humans, prior to</p> <p>6 launching the TVT-Secur product?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Go ahead.</p> <p>10 A. None.</p> <p>11 Q. Did Ethicon do any studies of the</p> <p>12 TVT-Secur product prior to launch other than the</p> <p>13 interim First Human Use Study?</p> <p>14 A. There was a sheep study that was done in</p> <p>15 live sheep that was done in 2004. There was a</p> <p>16 sheep cadaver study that was performed in 2005.</p> <p>17 And then there were human cadaver studies that</p> <p>18 were -- that were performed.</p> <p>19 Q. Now, the live sheep study, was that done</p> <p>20 on -- was that study performed using the TVT-Secur</p> <p>21 product in final form as it was sold to doctors for</p> <p>22 implantation into patients?</p> <p>23 A. No, it was not.</p> <p>24 Q. What was that -- what was the -- strike</p>

41 (Pages 158 to 161)

Bruce Alan Rosenzweig, M.D.

Page 162	Page 164
<p>1 that.</p> <p>2 What was the test or tested product in</p> <p>3 the TVT -- strike that.</p> <p>4 What product was tested in the sheep</p> <p>5 study on live sheep?</p> <p>6 A. It was called the TVT X, which was at</p> <p>7 that point 12 centimeters long and had a different</p> <p>8 fleece end. The original embodiment had four</p> <p>9 finger projections. During the study they changed</p> <p>10 that to three finger projections.</p> <p>11 Q. Do you have an opinion whether or not</p> <p>12 the TVT X live sheep study supported the safety and</p> <p>13 efficacy of the TVT-Secur product?</p> <p>14 A. Yes, I do have an opinion.</p> <p>15 Q. What is that opinion?</p> <p>16 A. No, it did not support it.</p> <p>17 Q. Did any of the animal studies, the live</p> <p>18 sheep study or the study that was done in sheep</p> <p>19 cadavers, and by cadavers, you understand I mean</p> <p>20 dead sheep, did any of those -- either of those</p> <p>21 studies support the safety or efficacy of the</p> <p>22 TVT-Secur product to be used in human patients?</p> <p>23 A. No, it did not.</p> <p>24 Q. Why not?</p>	<p>1 A. Martin Weisberg.</p> <p>2 Q. Mark Weisberg. Thank you.</p> <p>3 You've reviewed the testimony of</p> <p>4 Dr. Mark --</p> <p>5 A. Martin.</p> <p>6 Q. -- Martin Weisberg?</p> <p>7 A. Yes.</p> <p>8 Q. And did you review -- strike that.</p> <p>9 Do you have an understanding based on</p> <p>10 your review of Dr. Martin Weisberg's deposition</p> <p>11 whether or not he understood what the risks were</p> <p>12 associated with the TVT-Secur product prior to</p> <p>13 launch?</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. I want to do a side-by-side of</p> <p>19 Exhibit P0871. Do you have P0871?</p> <p>20 A. Yes.</p> <p>21 Q. That's the TVT-Secur IFU? Do you have</p> <p>22 that in front of you?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And if you turn to the -- to</p>
Page 163	Page 165
<p>1 A. It was not designed to look at safety</p> <p>2 and effectiveness in the humans of the final</p> <p>3 product that was sold starting September 20, 2006.</p> <p>4 Q. Turning back to P1177, if you turn with</p> <p>5 me to Bates number ending in 5241, there is a list</p> <p>6 of potential complications that are identified.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And did Ethicon have any human data</p> <p>10 related to or specifically related to the TVT-Secur</p> <p>11 product prior to identifying these potential</p> <p>12 complications with the TVT-Secur product?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY THE WITNESS:</p> <p>15 A. No, they did not.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Did Ethicon identify these potential</p> <p>18 complications prior to ever conducting a human</p> <p>19 study?</p> <p>20 A. A live human study? No.</p> <p>21 Q. And have you also reviewed -- strike</p> <p>22 that.</p> <p>23 You testified that you reviewed the</p> <p>24 testimony of Dr. David Weisberg?</p>	<p>1 ETH.MESH.02340589 of Exhibit P871, you'll see a</p> <p>2 "Adverse Reactions" section?</p> <p>3 A. Yes.</p> <p>4 Q. And does the potential complications</p> <p>5 that were listed by Martin Weisberg in his Clinical</p> <p>6 Expert Report dated December 2, 2005 match the</p> <p>7 "Adverse Reactions" section which made it into the</p> <p>8 final TVT-Secur IFU?</p> <p>9 A. Yes.</p> <p>10 Q. Do you have an opinion whether or not</p> <p>11 the "Adverse Reactions" section in the IFU contains</p> <p>12 a complete and accurate disclosure of the risks</p> <p>13 that Ethicon knew or should have known about prior</p> <p>14 to launching the TVT-Secur product?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes, I do have an opinion.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what's that opinion?</p> <p>20 A. It is an incomplete list of all the</p> <p>21 adverse reactions that are associated with the</p> <p>22 TVT-Secur device.</p> <p>23 Q. I'm going to hand you P2377. Do you</p> <p>24 have P2377 in your binder?</p>

42 (Pages 162 to 165)

Bruce Alan Rosenzweig, M.D.

Page 166	Page 168
<p>1 A. Yes.</p> <p>2 MR. THORNBURGH: I will hand defense counsel</p> <p>3 P2377. Thank you.</p> <p>4 And if you can, put P2377 side by side</p> <p>5 on the screen with Exhibit P1177, ETH.MESH ending</p> <p>6 in 241, and the "Adverse Reactions" section in P871</p> <p>7 of the IFU ending in Bates No. 589. Can you put</p> <p>8 all three of those documents up.</p> <p>9 MR. SNELL: Note my objection to P1640.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Doctor, what is P2377?</p> <p>12 A. It is an exhibit from Dr. Weisberg's</p> <p>13 testimony.</p> <p>14 Q. What did Dr. Weisberg testify to</p> <p>15 concerning Exhibit P2377?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. That these were adverse reactions that</p> <p>19 were known since the time of launch of the TVT</p> <p>20 device.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And when was the TVT device launched?</p> <p>23 A. Either the end of -- very end of 1997 or</p> <p>24 very early in 1998.</p>	<p>1 identified in 2377, which were known by him in --</p> <p>2 prior to launching the TVT product, could have been</p> <p>3 added to the TVT IFUs?</p> <p>4 MR. SNELL: Object. Object. Go ahead.</p> <p>5 BY THE WITNESS:</p> <p>6 A. These additional adverse reactions could</p> <p>7 have been added to the Instructions for Use.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Do you have an opinion whether or not it</p> <p>10 would have been reasonable and feasible for Ethicon</p> <p>11 to disclose in the TVT-Secur IFU the adverse</p> <p>12 reactions that are identified in 2377?</p> <p>13 MR. SNELL: Object. Go ahead.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes, I have an opinion.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. What's that opinion?</p> <p>18 A. That it would have been reasonable and</p> <p>19 feasible to add these to the Instructions for Use.</p> <p>20 Q. And the -- did Ethicon include the</p> <p>21 adverse reactions that Weisberg testified he knew</p> <p>22 of and were -- would have been feasible and</p> <p>23 reasonable in to add to -- strike that.</p> <p>24 Did Dr. -- did Ethicon include the</p>
Page 167	Page 169
<p>1 Q. And, so, this was six years or eight</p> <p>2 years prior to launching the TVT-Secur product?</p> <p>3 A. Correct.</p> <p>4 Q. And what did Dr. -- so, I think you</p> <p>5 testified -- I'm going to read back, make sure I've</p> <p>6 got it here -- but you've testified that</p> <p>7 Exhibit 2377 reflects the adverse reactions that</p> <p>8 were known since the time of launch of the</p> <p>9 TVT-Secur device. Is that your testimony?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. If I recall Dr. Weisberg's testimony,</p> <p>13 that is what I think he testified to.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. So, based on your review of</p> <p>16 Dr. Weisberg's testimony, did Dr. Weisberg admit</p> <p>17 that he had an understanding that these risks</p> <p>18 identified in P2377 were known by him?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And what did Dr. Weisberg testify with</p> <p>24 respect to whether or not these adverse reactions</p>	<p>1 adverse reactions identified in P2377 within the</p> <p>2 TVT-Secur IFU?</p> <p>3 A. No, they never did.</p> <p>4 Q. And are the -- if we look at P871, which</p> <p>5 is the TVT-Secur IFU, Bates No. 589, are these the</p> <p>6 adverse reactions that Ethicon put into the</p> <p>7 TVT-Secur IFU back in 2006 when they launched the</p> <p>8 TVT-Secur product?</p> <p>9 A. Yes.</p> <p>10 Q. Did Ethicon ever change the IFU section</p> <p>11 on adverse reactions from the time they launched</p> <p>12 the TVT-Secur product until the time that they</p> <p>13 stopped selling the product in 2012?</p> <p>14 A. No, they did not.</p> <p>15 Q. Do you have an opinion whether or not</p> <p>16 Ethicon should have included the adverse reactions</p> <p>17 that are identified in 2377 in their IFU for the</p> <p>18 Secur product?</p> <p>19 A. Yes, I do have an opinion.</p> <p>20 Q. What's that opinion?</p> <p>21 A. That these should have been included in</p> <p>22 the Instructions for Use.</p> <p>23 Q. And why should they have included the</p> <p>24 adverse reactions identified in 2377?</p>

Bruce Alan Rosenzweig, M.D.

Page 170	Page 172
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Because these are adverse reactions that</p> <p>4 are -- have been known to be associated with the</p> <p>5 TVT-Secur device. That information should be given</p> <p>6 to physicians in the Instructions for Use. The</p> <p>7 Instructions for Use should include all of the</p> <p>8 known risks associated with the device.</p> <p>9 The Instructions for Use should not</p> <p>10 downplay the risks associated with the device or</p> <p>11 obscure risks that are associated with the device</p> <p>12 because doctors have different treatments and</p> <p>13 devices that they can use to treat a particular</p> <p>14 condition and patients have choices about the type</p> <p>15 of surgeries they have and the type of devices that</p> <p>16 are used to treat medical conditions and doctors</p> <p>17 cannot have an informed decision with a -- with a</p> <p>18 woman if they are not aware of all the potential</p> <p>19 adverse reactions associated with the device.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Did Ethicon ever change the list of</p> <p>22 potential complications that they identified in the</p> <p>23 December 2005 Clinical Expert Report until the date</p> <p>24 that they launched the TVT-Secur on the product --</p>	<p>1 data from the First Human Use Study in the</p> <p>2 "Warnings" section of the IFU for the TVT-Secur</p> <p>3 before they launched the product?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes, the Instructions for Use should</p> <p>7 include the frequency, severity, treatability and</p> <p>8 permanency of adverse reactions that were</p> <p>9 associated with a device.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. If manufacturing companies like</p> <p>12 Ethicon -- do you have an opinion whether or not</p> <p>13 manufacturers -- do you have an opinion whether or</p> <p>14 not medical device manufacturers such as Ethicon</p> <p>15 and Johnson & Johnson should be complete and</p> <p>16 accurate in their disclosure of safety information?</p> <p>17 A. Yes, I have an opinion.</p> <p>18 Q. Do you have an opinion whether or not</p> <p>19 manufacturers like Ethicon and Johnson & Johnson</p> <p>20 should be complete and accurate in their disclosure</p> <p>21 of efficacy information?</p> <p>22 A. Yes, I have an opinion.</p> <p>23 Q. And what are the -- what are your</p> <p>24 opinions with respect to both safety and efficacy?</p>
Page 171	Page 173
<p>1 on to the market in September of 2006?</p> <p>2 A. No, they did not.</p> <p>3 Q. Would it have been reasonable and</p> <p>4 feasible for Ethicon to make revisions to those</p> <p>5 potential complications?</p> <p>6 MR. SNELL: Object. Go ahead.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Did Ethicon have human data from their</p> <p>11 First Human Use Study that they could have looked</p> <p>12 at to determine whether or not changes could</p> <p>13 have -- could or should have been made to the</p> <p>14 TVT-Secur "Adverse Reactions" section in the IFU?</p> <p>15 A. Yes.</p> <p>16 Q. And what was that exactly?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. They had the First Human Use data,</p> <p>20 again, that showed a 30% failure rate and a 60%</p> <p>21 complication rate.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Do you have an opinion whether or not</p> <p>24 Ethicon should have provided the information or the</p>	<p>1 A. That they should --</p> <p>2 MR. SNELL: Object. Go ahead.</p> <p>3 BY THE WITNESS:</p> <p>4 A. They should disclose all the safety and</p> <p>5 efficacy information that they have available to</p> <p>6 them.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. As a physician treating patients and</p> <p>9 discussing with patients surgical options for the</p> <p>10 treatment of stress urinary incontinence, would you</p> <p>11 have expected Ethicon to disclose to you in their</p> <p>12 IFU or otherwise that their First Human Use Study</p> <p>13 demonstrated that 60% of the patients could</p> <p>14 experience or were at risk of experiencing</p> <p>15 complications?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. From the TVT-Secur product.</p> <p>19 A. Yes, I would have expected them to</p> <p>20 disclose that.</p> <p>21 Q. As a physician treating patients and</p> <p>22 discussing with patients surgical options for the</p> <p>23 treatment of stress urinary incontinence, would you</p> <p>24 have expected Ethicon to disclose to you in their</p>

44 (Pages 170 to 173)

Bruce Alan Rosenzweig, M.D.

Page 174	Page 176
<p>1 IFU or otherwise that the First Human Use Study</p> <p>2 demonstrated a 30% failure rate?</p> <p>3 MR. SNELL: Object.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what is that opinion?</p> <p>8 A. I would have expected that they would</p> <p>9 have disclosed that.</p> <p>10 Q. Why would you have expected as a doctor</p> <p>11 treating patients that Ethicon would disclose that</p> <p>12 information to you?</p> <p>13 MR. SNELL: Continuing objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Because that is information that is</p> <p>16 important for me to have so I can have a discussion</p> <p>17 with the patient regarding the safety and efficacy</p> <p>18 of a given device because doctors have multiple</p> <p>19 devices at their disposable -- at their disposal to</p> <p>20 treat conditions or have different surgical</p> <p>21 procedures that can treat a medical condition and</p> <p>22 they need all the information about a particular</p> <p>23 device or procedure at their disposal to decide</p> <p>24 whether or not they are going to offer that to an</p>	<p>1 A. Yes, I have an opinion.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. What's that opinion?</p> <p>4 A. It put patients at risk.</p> <p>5 Q. Do you have an opinion whether or not it</p> <p>6 was appropriate for Ethicon or Johnson & Johnson to</p> <p>7 withhold the safety and efficacy data from</p> <p>8 physicians concerning the data they had prior to</p> <p>9 launch that they received from the First Human Use</p> <p>10 Study?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes, I have an opinion.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What's that opinion?</p> <p>16 A. That that information should not have</p> <p>17 been withheld from physicians.</p> <p>18 Q. What's the next document in your binder,</p> <p>19 Dr. Rosenzweig, that you'd like to discuss?</p> <p>20 A. P0279.</p> <p>21 Q. And can you identify what P0279 is?</p> <p>22 A. Yes.</p> <p>23 MR. SNELL: Can I have a copy.</p> <p>24 BY THE WITNESS:</p>
Page 175	Page 177
<p>1 individual patient and the individual patient needs</p> <p>2 that information to decide if they want that</p> <p>3 individual treatment.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Why does any of this matter, Doctor?</p> <p>6 A. It matters for patient --</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. It matters for patient safety.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. What can happen to patients if companies</p> <p>12 like Ethicon and Johnson & Johnson are not complete</p> <p>13 and accurate about the safety and efficacy of</p> <p>14 permanent implantable devices that they're selling?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Patients can get harmed.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Do you have an opinion whether or not</p> <p>20 Johnson & Johnson and Ethicon's failure to disclose</p> <p>21 the safety and efficacy data from the First Human</p> <p>22 Use Study put patients at risk of suffering harm?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>	<p>1 A. It is an e-mail between Gary Borkes, who</p> <p>2 we've discussed earlier, and Mark Yale, who is a</p> <p>3 safety officer at Ethicon, describing the TVT</p> <p>4 design review, design validation from February 9,</p> <p>5 2006.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And how is Exhibit P0279 significant, if</p> <p>8 at all, to your opinions in this case?</p> <p>9 A. It is a discussion between key Ethicon</p> <p>10 employees regarding the design validation process</p> <p>11 and the -- about the pressure that they're under to</p> <p>12 get the design validation process done and that if</p> <p>13 the design validation process is not done</p> <p>14 completely, appropriately and accurately, that</p> <p>15 there can be significant consequences associated</p> <p>16 with that.</p> <p>17 Q. What are some of the reasons why design</p> <p>18 validation process may not be done appropriately?</p> <p>19 A. Can you repeat the question?</p> <p>20 Q. Yes, sure. What are some of the reasons</p> <p>21 why a design validation process or study may not</p> <p>22 get done appropriately?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>

45 (Pages 174 to 177)

Bruce Alan Rosenzweig, M.D.

Page 178	Page 180
<p>1 A. If there's pressure to get a project</p> <p>2 completed quickly, then a design validation process</p> <p>3 might not be done as completely and accurately due</p> <p>4 to time constraints.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Do you have an opinion whether or not</p> <p>7 Ethicon's design validation process was done</p> <p>8 appropriately?</p> <p>9 A. Yes, I have an opinion.</p> <p>10 Q. What's that opinion?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. It was not done completely and</p> <p>14 appropriately.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Do you have an opinion whether or not</p> <p>17 Ethicon's -- do you have a -- strike that.</p> <p>18 Do you have an opinion why that</p> <p>19 occurred, based on your review of Ethicon's</p> <p>20 documents?</p> <p>21 A. That there was immense pressure to move</p> <p>22 the process along so that they could get the</p> <p>23 product launched as quickly as they -- as they</p> <p>24 could.</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. This supports my opinions that the</p> <p>4 design validation process was rushed; that all the</p> <p>5 characteristics of the TVT-Secur device that were</p> <p>6 unreasonably unsafe, which led to complications,</p> <p>7 adverse events and harm to patients, were not</p> <p>8 identified prior to launch; that the design</p> <p>9 characteristics that made it unreasonably</p> <p>10 ineffective and led to recurrence or inability to</p> <p>11 treat stress incontinence were not found before</p> <p>12 launch; and that there was intense pressure from</p> <p>13 the president down through the ranks to speed the</p> <p>14 process along as quickly as possible to get the</p> <p>15 product on the market.</p> <p>16 Q. You just said a lot. So, I want to</p> <p>17 break that down, and here's how I want to do it.</p> <p>18 How would you describe the opinion that</p> <p>19 you just expressed in one sentence?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. There was intense pressure to get the</p> <p>23 product to market.</p> <p>24 BY MR. THORNBURGH:</p>
Page 179	Page 181
<p>1 Q. And if we look at Exhibit P0279, I want</p> <p>2 to look -- direct your attention to the bottom half</p> <p>3 of the first page, the e-mail from Mark Yale.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And is this part of the e-mail that you</p> <p>7 just discussed?</p> <p>8 A. Yes.</p> <p>9 Q. And you'll see it says, "Can you give me</p> <p>10 insight into where Raimo and Dan are at. For the</p> <p>11 last two days at the leadership meeting I had</p> <p>12 everyone from Renee Selman on down pulling me</p> <p>13 'aside' asking me how the proverbial 'we' get this</p> <p>14 project done. There is immense political pressure</p> <p>15 here and I need to actively manage the overall QE</p> <p>16 response."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: Object; leading.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. First of all, who is Renee Selman?</p> <p>22 A. The president of Ethicon.</p> <p>23 Q. And how does this statement here by Mark</p> <p>24 Yale support your opinions in this case?</p>	<p>1 Q. And the e-mail goes on by Mark Yale and</p> <p>2 says, "Bottom line if there is a big steaming pile</p> <p>3 here (as I suspect), I need to know ASAP and push</p> <p>4 back hard on whomever to fix."</p> <p>5 Did I read that correctly?</p> <p>6 MR. SNELL: Object and leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. How, if at all, does this statement by</p> <p>11 Mark Yale support your opinions in this case?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. As of February 9, 2006, it was suspected</p> <p>15 that there could be design characteristics</p> <p>16 associated with the device that either made it</p> <p>17 unreasonably unsafe or led it to be unreasonably</p> <p>18 ineffective in treating the device; that the head</p> <p>19 of -- of quality wanted to know that as soon as</p> <p>20 possible so that they could find out what those</p> <p>21 design characteristics were to try to fix those</p> <p>22 design characteristics to try to make a reasonably</p> <p>23 safe and effective device.</p> <p>24 BY MR. THORNBURGH:</p>

46 (Pages 178 to 181)

Bruce Alan Rosenzweig, M.D.

Page 182	Page 184
<p>1 Q. Do you have an opinion whether or not</p> <p>2 women deserve better conduct from medical device</p> <p>3 companies like Ethicon and Johnson & Johnson than</p> <p>4 what is being described here in this document?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. What's that opinion?</p> <p>10 A. That they do deserve better</p> <p>11 consideration than just top executives at Ethicon</p> <p>12 discussing that there are more likely than not big</p> <p>13 problems associated with the device design,</p> <p>14 characteristics that are unreasonably unsafe or</p> <p>15 make it unreasonably ineffective, and that they</p> <p>16 are -- those are being ignored and a product is</p> <p>17 being rushed to market.</p> <p>18 Q. Did Ethicon ever fix any of the problems</p> <p>19 with their design validation?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. No, they did not.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Based on your review of the documents,</p>	<p>1 pressure on their employees in order to rush a</p> <p>2 product through to get it launched?</p> <p>3 MR. SNELL: Objection.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes, I have an opinion.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. What's that opinion?</p> <p>8 A. They should not be doing that.</p> <p>9 Q. Do you have an opinion based on your</p> <p>10 review of the medical -- review of Ethicon's</p> <p>11 internal documents the purpose for putting</p> <p>12 political pressure on employees in order to get the</p> <p>13 TVT-Secur launched?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Can you repeat the question again.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Yeah, no problem, no problem. That's</p> <p>19 probably why it was objected to.</p> <p>20 Do you know whether or not the documents</p> <p>21 that we had reviewed previously, whether or not the</p> <p>22 need to get a mini-sling to the market first played</p> <p>23 a role in Ethicon's executives putting political</p> <p>24 pressure on its employees to get the TVT-Secur</p>
Page 183	Page 185
<p>1 did Ethicon ever change its design before they</p> <p>2 launched the product on the market from</p> <p>3 February 2006 until September of 2006?</p> <p>4 A. No, they did not.</p> <p>5 Q. And why is that important? Is that</p> <p>6 important to your opinion?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Why is that?</p> <p>9 A. In February 9, 2006, there were -- was</p> <p>10 discussion about design characteristics that made</p> <p>11 it unreasonably unsafe or unreasonably ineffective.</p> <p>12 Those characteristics were not identified.</p> <p>13 The product was placed on the market.</p> <p>14 It was found to be unreasonably unsafe or</p> <p>15 unreasonably ineffective in treating stress urinary</p> <p>16 incontinence and led to complications in women</p> <p>17 which could have and should have been identified</p> <p>18 during this time period and either fixed prior to</p> <p>19 launch or launch either stopped completely and the</p> <p>20 product never put on the market or at least</p> <p>21 addressed and identified.</p> <p>22 Q. Do you have an opinion whether or not</p> <p>23 medical device companies like Ethicon and</p> <p>24 Johnson & Johnson should ever put immense political</p>	<p>1 product launched?</p> <p>2 MR. SNELL: Objection, now including leading.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And what's that opinion?</p> <p>7 A. That the main purpose of putting the</p> <p>8 intense political pressure to get the product</p> <p>9 launched was to stay ahead of the competition and</p> <p>10 be the first to market.</p> <p>11 Q. And if you look at the first sentence in</p> <p>12 the e-mail response from Gary Borkes on February 9,</p> <p>13 2006, he writes, "Mark - yes - we should talk -</p> <p>14 there's a great deal of spin happening at this</p> <p>15 point, unfortunately."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 MR. SNELL: Object; leading.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. How is, if at all, that statement from</p> <p>21 Gary Borkes relevant or significant to your</p> <p>22 opinions?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>

47 (Pages 182 to 185)

Bruce Alan Rosenzweig, M.D.

Page 186	Page 188
<p>1 A. It is important that any characteristics 2 of a device that are found to be unreasonably 3 unsafe or make a device unreasonably ineffective 4 are described in detail and not spun in a way that 5 makes it more palatable. 6 Those characteristics should be 7 described and fixed and either the device not 8 launched or those characteristics fixed before a 9 product is launched. 10 BY MR. THORNBURGH: 11 Q. Okay. And what is -- is there anything 12 else relevant to that last exhibit we were looking 13 at to your opinions? 14 A. No. 15 Q. What's the next exhibit that you want to 16 discuss with the jury? 17 A. P0542. 18 Q. And can you explain to the ladies and 19 gentlemen of the jury what P0542 is? 20 A. It is an e-mail from Allison London 21 Brown, who is the worldwide launch coordinator for 22 the TVT-Secur, and Dan Smith, the lead engineer and 23 co-patent holder for the TVT-Secur, discussing the 24 TVT-Secur device as a new product or technique and</p>	<p>1 Based on Exhibit P0542, do you have an 2 opinion whether or not Ethicon knew or should have 3 known that it would be inappropriate for Ethicon to 4 rely on data from its other TVT products? 5 MR. SNELL: Objection. 6 BY THE WITNESS: 7 A. Yes, I do have an opinion. 8 BY MR. THORNBURGH: 9 Q. And what is that opinion? 10 A. Yes, it would -- this communication 11 between key Ethicon employees does show an 12 understanding that the TVT-Secur is a new product 13 and therefore the data from their other full-length 14 products would not be applicable to the -- the 15 short, stiff, rigid mesh that had never been used 16 before, the fleece tips that had never been used 17 for, the sharp arrowhead introducer that had never 18 been used before. 19 Q. Let me just make sure I understand 20 really quick. If we look at P0542. 21 MR. THORNBURGH: Tom, if you could blow up the 22 section under "TVT-Secur." 23 BY MR. THORNBURGH: 24 Q. It says, "TVT-Secur is a new</p>
Page 187	Page 189
<p>1 has little relationship with the data that had been 2 obtained from the full-length retropubic sling that 3 I discussed earlier in my testimony. 4 Q. How, if at all, is Exhibit P0542 5 relevant to your opinions in this case? 6 A. This is relevant to my opinions that -- 7 that the data on the full-length TVT Retropubic 8 cannot be used to justify how the TVT-Secur will 9 react inside of a woman as far as safety and 10 efficacy goes. 11 Q. So, if Ethicon or if at least if Allison 12 London Brown felt that Ethicon could not rely on 13 the data from the other TVT Retropubic full-length 14 product on the market, do you have an opinion as to 15 what Ethicon could have done? 16 MR. SNELL: Objection. Go ahead. 17 BY THE WITNESS: 18 A. Ethicon could have done studies that 19 could get the database that they had for the TVT, 20 full-length TVT for the TVT-Secur to know how it 21 would perform in women from a safety and efficacy 22 perspective. 23 BY MR. THORNBURGH: 24 Q. Based on Exhibit P4 -- sorry.</p>	<p>1 product/technique and therefore there is little 2 relationship to the TVT 7-year data." 3 Did I read that correctly? 4 MR. SNELL: Objection; leading. 5 BY THE WITNESS: 6 A. Yes. 7 BY MR. THORNBURGH: 8 Q. Let me just make sure I ask it again. 9 This statement here that Tom has blown 10 up under the "TVT-Secur" section says, "TVT-Secur 11 is a new product/technique and therefore there is 12 little relationship to the 7-year database other 13 than it is the same Prolene mesh." 14 Did I read that correctly? 15 MR. SNELL: Same objection. 16 BY THE WITNESS: 17 A. Yes. 18 BY MR. THORNBURGH: 19 Q. And do you agree with that statement? 20 A. Yes. 21 Q. Now, I understand you're a paid expert 22 for the Plaintiffs, is that correct? 23 A. Correct. 24 Q. And you hold this same opinion, is that</p>

Bruce Alan Rosenzweig, M.D.

Page 190	Page 192
<p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. So, these aren't your words, right?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Are these your words?</p> <p>7 MR. SNELL: Same objection.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Let me ask again.</p> <p>10 Are the words that we see on page -- the</p> <p>11 first page of P0542, are those your words?</p> <p>12 MR. SNELL: Objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No. This comes from an internal Ethicon</p> <p>15 document.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And are those words that you agree with?</p> <p>18 A. Yes.</p> <p>19 Q. And how many years were those written,</p> <p>20 those words written by Ethicon's employees before</p> <p>21 you were ever involved in this litigation?</p> <p>22 A. This is from 2006.</p> <p>23 Q. Are the words in any of these documents</p> <p>24 that we're looking at, are those your words?</p>	<p>1 reliance list.</p> <p>2 MR. SNELL: That's fine. Then I'll say I'm</p> <p>3 wrong. We are trying to run word searches on this</p> <p>4 large reliance list and number searches and it's</p> <p>5 just not showing up.</p> <p>6 MR. THORNBURGH: Gotcha.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Sorry, Doctor. What's the next exhibit</p> <p>9 that you'd like to discuss with the ladies and</p> <p>10 gentlemen of the jury?</p> <p>11 A. P0716.</p> <p>12 Q. And what's the date of this document?</p> <p>13 A. This is an e-mail string from June 20,</p> <p>14 2006.</p> <p>15 Q. Is this before or after the TVT-Secur</p> <p>16 product was launched?</p> <p>17 A. It is approximately three months prior</p> <p>18 to launch.</p> <p>19 Q. And do you -- strike that.</p> <p>20 How does Exhibit P0716 support, if at</p> <p>21 all, your opinions in this case?</p> <p>22 A. This supports my opinion that the</p> <p>23 TVT-Secur device should have been studied in</p> <p>24 randomized controlled trials before launch and</p>
Page 191	Page 193
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No, these are from internal Ethicon</p> <p>4 documents.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And do you agree with some of the words</p> <p>7 and opinions that are being expressed in the</p> <p>8 documents that we're looking at?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. What's the next exhibit you'd like to</p> <p>14 discuss with the ladies and gentlemen of the jury?</p> <p>15 A. P0716.</p> <p>16 MR. SNELL: Just for the record I didn't see</p> <p>17 P0279 on his exhibit list. We have been checking.</p> <p>18 So, I move to strike all testimony about it.</p> <p>19 MR. THORNBURGH: And just for the record it's</p> <p>20 on there. We can address this later on.</p> <p>21 MR. SNELL: Oh, yeah.</p> <p>22 MR. THORNBURGH: So were the other documents</p> <p>23 that you guys identified. We went and looked at</p> <p>24 lunch. Those other documents are also on the</p>	<p>1 doing so did not allow doctors and scientists to</p> <p>2 know the device characteristics that made it</p> <p>3 unreasonably unsafe and also unreasonably</p> <p>4 ineffective.</p> <p>5 Q. What part of this document supports your</p> <p>6 opinion that Ethicon should have studied in</p> <p>7 randomized controlled trials the TVT-Secur before</p> <p>8 they launched it?</p> <p>9 A. Well, this e-mail describes that two</p> <p>10 very well-known doctors and Key Opinion Leaders,</p> <p>11 Dr. Nilsson and Dr. Artibani, expressed their</p> <p>12 worries about Ethicon launching TVT-Secur with no</p> <p>13 clinical data other than 50 patients with five</p> <p>14 weeks of follow-up.</p> <p>15 Q. And let me stop you right there for a</p> <p>16 moment.</p> <p>17 Who is Professor Nilsson?</p> <p>18 A. Dr. Nilsson is one of the co-inventors</p> <p>19 of the TVT Retropubic, probably has the most</p> <p>20 experience with midurethral slings and is a Key</p> <p>21 Opinion Leader for Ethicon.</p> <p>22 Q. So, Dr. Nilsson was the co-inventor of</p> <p>23 the TVT-Secur retropubic device?</p> <p>24 A. Correct.</p>

49 (Pages 190 to 193)

Bruce Alan Rosenzweig, M.D.

Page 194	Page 196
<p>1 MR. SNELL: Objection.</p> <p>2 MR. THORNBURGH: Sorry. Strike that. Let me</p> <p>3 strike that. Withdraw that.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Who was Dr. Nilsson?</p> <p>6 A. Dr. Nilsson was a contemporary with the</p> <p>7 inventor of the TVT Retropubic. From my</p> <p>8 understanding, he was with Dr. Ulmsten during the</p> <p>9 early -- the earliest clinical trials with the</p> <p>10 TVT Retropubic.</p> <p>11 Q. And did he publish -- was he a</p> <p>12 co-publisher of data concerning the TVT Retropubic,</p> <p>13 the first generation TVT device?</p> <p>14 A. Yes.</p> <p>15 Q. And who is Dr. Professor Artibani?</p> <p>16 A. Dr. Artibani is a pelvic surgeon from</p> <p>17 Italy who is also a Key Opinion Leader for Ethicon,</p> <p>18 very well-known pelvic surgeon.</p> <p>19 Q. Both of them -- are both Professor</p> <p>20 Nilsson and Professor Artibani licensed medical</p> <p>21 doctors?</p> <p>22 A. Yes.</p> <p>23 Q. Or were they when they were alive? Were</p> <p>24 they medical doctors, based on your understanding?</p>	<p>1 A. I agree.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And are those your words?</p> <p>4 A. No. Those are the concerns expressed by</p> <p>5 Dr. Nilsson and Dr. Artibani.</p> <p>6 MR. THORNBURGH: And if we go further down on</p> <p>7 Bates number 851, Tom, if you can blow up where it</p> <p>8 begins with "I'm a bit concerned."</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Harel Gadot. Who is Harel Gadot?</p> <p>11 A. He is the European marketing manager.</p> <p>12 Q. And for Ethicon?</p> <p>13 A. Yes.</p> <p>14 Q. And Harel Gadot writes, "I'm a bit</p> <p>15 concerned that by canceling the RCT we will hurt</p> <p>16 our image in their eyes, especially after we've</p> <p>17 communicated this to them and worked with them to</p> <p>18 resolve any concerns they had associating with</p> <p>19 TVT-Secur. I believe the success of the launch of</p> <p>20 TVT-Secur across EMEA" -- do you understand what</p> <p>21 EMEA stands for?</p> <p>22 A. Yes. It's Europe Middle East and</p> <p>23 Africa.</p> <p>24 Q. "And probably other parts WW." Is that</p>
Page 195	Page 197
<p>1 A. Yes.</p> <p>2 Q. And as we see on page 2 of this</p> <p>3 Exhibit 716, Bates number ending in 851, midway</p> <p>4 through this page it says, "Regarding the proposed</p> <p>5 RCT," and that's randomized controlled trial, is</p> <p>6 that correct?</p> <p>7 A. Yes.</p> <p>8 Q. "Both Professor Nilsson and Professor</p> <p>9 Artibani expressed their worries about us launching</p> <p>10 TVT-Secur with no clinical data (other than the 50</p> <p>11 patients, 5 week follow-up)."</p> <p>12 Did I read that correctly?</p> <p>13 MR. SNELL: Object; leading.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And do you agree or disagree with the</p> <p>18 concerns that are being expressed by Professor</p> <p>19 Nilsson and Professor Artibani concerning releasing</p> <p>20 the TVT-Secur with no randomized controlled trial</p> <p>21 or clinical data other than the 50 patient,</p> <p>22 five-week follow-up study?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>	<p>1 worldwide?</p> <p>2 A. Yes.</p> <p>3 Q. "Will depend heavily on those two Key</p> <p>4 Opinion Leaders and their willingness to assist us</p> <p>5 with our future communication plans. Therefore I</p> <p>6 would strongly recommend to find a way not to</p> <p>7 cancel completely the proposed RCT."</p> <p>8 Did I read that correctly?</p> <p>9 MR. SNELL: Objection; leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And how, if at all, does -- do those</p> <p>14 statements from Dr. Harel Gadot support your</p> <p>15 opinion?</p> <p>16 A. They support my opinion that randomized</p> <p>17 controlled trials should have been done prior to</p> <p>18 launch of the TVT-Secur so that the design</p> <p>19 characteristics that made it unreasonably unsafe</p> <p>20 and unreasonably ineffective would have been known</p> <p>21 prior to launch and either the product not launched</p> <p>22 or the design characteristics fixed to make it</p> <p>23 reasonably safe and reasonably effective.</p> <p>24 Q. Do you know whether or not Ethicon</p>

Bruce Alan Rosenzweig, M.D.

Page 198	Page 200
<p>1 ultimately at least sponsored randomized controlled</p> <p>2 trials?</p> <p>3 A. There were initiator -- excuse me --</p> <p>4 investigator-initiated studies that were co-funded</p> <p>5 by Ethicon.</p> <p>6 Q. And do you know whether or not those</p> <p>7 investigator-initiated studies that were sponsored</p> <p>8 at least financially by Ethicon supported or didn't</p> <p>9 support the safety and efficacy of the TVT-Secur</p> <p>10 product?</p> <p>11 A. There are studies that were</p> <p>12 investigator-initiated studies that did not support</p> <p>13 the safety and efficacy of the TVT-Secur.</p> <p>14 Q. And we will talk about some of those</p> <p>15 studies, but we've got to take a break for changing</p> <p>16 the tape.</p> <p>17 THE VIDEOGRAPHER: Okay. The time is 2:02</p> <p>18 p.m. This is the end of Tape 2 and we're going off</p> <p>19 the video record.</p> <p>20 (WHEREUPON, a recess was had</p> <p>21 from 2:02 to 2:13 p.m.)</p> <p>22 THE VIDEOGRAPHER: The time is 2:13 p.m. This</p> <p>23 is the beginning of Tape 3 and we're back on the</p> <p>24 video record.</p>	<p>1 MR. SNELL: Opposing.</p> <p>2 MR. THORNBURGH: Opposing counsel.</p> <p>3 MR. SNELL: Opposing by stipulation.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Doctor, Exhibit P842, did you review and</p> <p>6 rely on that document before or that exhibit in</p> <p>7 rendering your opinions?</p> <p>8 A. Yes.</p> <p>9 Q. And what about Exhibit P842 did you rely</p> <p>10 upon?</p> <p>11 A. Again, this is a PowerPoint presentation</p> <p>12 which discusses the reasons for development, the</p> <p>13 needs for the TVT-Secur device. This is important</p> <p>14 in my opinions that the need for the device was not</p> <p>15 based on a -- safety and efficacy. These were</p> <p>16 based on financial decisions.</p> <p>17 There was a rush to market to fill a gap</p> <p>18 that competition to the products that Ethicon had</p> <p>19 on the market, and they felt -- Ethicon felt that</p> <p>20 if they did not have a TVT-Secur device on the</p> <p>21 market as soon as possible, they would lose market</p> <p>22 share.</p> <p>23 MR. SNELL: Object. Move to strike the state</p> <p>24 of mind. Go ahead.</p>
Page 199	Page 201
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Doctor, before we went off for break and</p> <p>3 throughout the vast majority of this deposition, we</p> <p>4 have been discussing your binder that you brought</p> <p>5 with you today, is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. And did you put together that binder?</p> <p>8 A. Yes.</p> <p>9 Q. Did you highlight the portions of the</p> <p>10 document that you felt were important for purposes</p> <p>11 of providing your opinions today?</p> <p>12 A. Yes.</p> <p>13 Q. And if I didn't ask you this already,</p> <p>14 maybe I thought it went without saying, but did you</p> <p>15 review and rely on all of those documents that are</p> <p>16 in your binder?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, what is the next exhibit you</p> <p>19 would like to discuss with the jury?</p> <p>20 A. This is a PowerPoint presentation, an</p> <p>21 internal Ethicon document, regarding the reasons</p> <p>22 for development of the TVT-Secur.</p> <p>23 MR. THORNBURGH: Okay. And let me give</p> <p>24 co-counsel a copy. Co-counsel. I take that back.</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And, Doctor, can you walk us through the</p> <p>3 different slides that you believe support your</p> <p>4 opinions and explain how those slides support your</p> <p>5 opinions, please.</p> <p>6 A. Yes. This is the fourth slide. It has</p> <p>7 a graph that we had looked at previously in the</p> <p>8 charter document showing the proposed decrease --</p> <p>9 it's actually the next page.</p> <p>10 Q. Okay. So, slide 5, is that where you're</p> <p>11 at?</p> <p>12 A. Correct.</p> <p>13 MR. SNELL: Let me just put an objection. I</p> <p>14 just want to object to the document on the record</p> <p>15 and I'll be quiet.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Actually let's go back to the one before</p> <p>18 that.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Slide 4 for the record.</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p> <p>23 A. What this shows is --</p> <p>24 Q. The fourth slide. They are not</p>

51 (Pages 198 to 201)

Bruce Alan Rosenzweig, M.D.

Page 202	Page 204
<p>1 numbered, but it's the fourth slide in</p> <p>2 Exhibit P842.</p> <p>3 I'm sorry. Go ahead, Doctor.</p> <p>4 A. Correct. What this document shows is a</p> <p>5 projection of what is happening with the market for</p> <p>6 the TVT Retropubic which continues to shrink.</p> <p>7 However, Gynecare will maintain the vast majority</p> <p>8 of that market.</p> <p>9 However, the obturator market is going</p> <p>10 to continue to grow and in order to be able to</p> <p>11 compete with their competitors, Gynecare needs to</p> <p>12 have a product that will be able to compete with</p> <p>13 this expanding market and the loss of the market of</p> <p>14 the retropubic slings.</p> <p>15 Q. Now, you've talked about the obturator</p> <p>16 and competition and market share. But can you</p> <p>17 explain for the ladies and gentlemen of the jury</p> <p>18 your understanding, based on your knowledge,</p> <p>19 training and experience as well as your review of</p> <p>20 Ethicon's documents, sort of what was going on at</p> <p>21 this time period with the different synthetic</p> <p>22 midurethral slings that were on the market and how</p> <p>23 that may or may not have impacted Ethicon's market</p> <p>24 share?</p>	<p>1 was the first to come to -- bring -- to bring a</p> <p>2 synthetic polypropylene mesh to the market for use</p> <p>3 in the retropubic approach?</p> <p>4 A. Yes. They were the first retropubic</p> <p>5 full-length polypropylene midurethral sling.</p> <p>6 Q. And do you know whether or not Ethicon</p> <p>7 was the first company to market a midurethral</p> <p>8 synthetic polypropylene sling to be implanted</p> <p>9 through the obturator approach?</p> <p>10 A. No, they were not.</p> <p>11 Q. They were not the first to come to</p> <p>12 market on the obturator, is that correct?</p> <p>13 A. Correct.</p> <p>14 Q. And did that -- do you have an</p> <p>15 understanding as to whether or not the fact that</p> <p>16 they were not the first to market the obturator</p> <p>17 device, how or if at all that impacted Ethicon's</p> <p>18 market share?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. They were losing market share to the</p> <p>22 obturator market prior to them putting an obturator</p> <p>23 sling on the market.</p> <p>24 BY MR. THORNBURGH:</p>
Page 203	Page 205
<p>1 MR. SNELL: Object. Go ahead.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Well, as this graphic shows is that the</p> <p>4 retropubic sling market, the one that goes behind</p> <p>5 the pubic bone that I've discussed earlier in</p> <p>6 testimony, was becoming a less significant part of</p> <p>7 the marketplace.</p> <p>8 The obturator sling, which I've</p> <p>9 discussed in earlier testimony, was becoming a</p> <p>10 larger part of the midurethral sling market.</p> <p>11 However, the portion of that market for Ethicon was</p> <p>12 not growing in the same proportion as the market</p> <p>13 was growing.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Let me stop you right there for a</p> <p>16 minute.</p> <p>17 Was Ethicon -- so, at this point in</p> <p>18 time, there was the retropubic slings that were on</p> <p>19 the market, is that correct?</p> <p>20 A. Correct.</p> <p>21 Q. Was there also the obturator slings that</p> <p>22 were on the market?</p> <p>23 A. Correct.</p> <p>24 Q. And do you know whether or not Ethicon</p>	<p>1 Q. Is this kind of what we were talking</p> <p>2 about earlier in the charter document?</p> <p>3 A. Yes.</p> <p>4 Q. And do you know or have an opinion as to</p> <p>5 how, based on your review of the records -- strike</p> <p>6 that.</p> <p>7 And, so, if we look at this slide,</p> <p>8 slide 4, it shows a "Past," "Now" and "Future"</p> <p>9 columns. Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And is that what you sort of explained</p> <p>12 that in the past where it says, it says Gynecare,</p> <p>13 they -- for the retropubic space, they had a -- the</p> <p>14 vast majority of the market share?</p> <p>15 A. Yes.</p> <p>16 Q. And you'll see that there is these sort</p> <p>17 of pie graphs are depicted in several different</p> <p>18 ways, either by color or by size, and you'll see in</p> <p>19 the "Past" that the size of the circle or pie is</p> <p>20 larger for Gynecare Retropubic than it is in the</p> <p>21 "Current" or "Future" columns.</p> <p>22 Do you see that?</p> <p>23 MR. SNELL: Object; leading.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 206	Page 208
<p>1 A. Correct.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And because I got an objection, can you</p> <p>4 describe sort of the past, current at the time of</p> <p>5 this PowerPoint, and future projection concerning</p> <p>6 the market share and how they're depicted in this</p> <p>7 document?</p> <p>8 A. The retropubic market will continue to</p> <p>9 decrease though Ethicare -- Gyne -- Ethicare (sic) will</p> <p>10 maintain its large portion of that market. The</p> <p>11 obturator market continues to grow, however</p> <p>12 Ethicon's share of that market is not -- is</p> <p>13 actually shrinking in the future.</p> <p>14 Q. Okay. And there is a little sort of --</p> <p>15 how do you describe that? A text bubble. What</p> <p>16 does that text bubble say and does or does that</p> <p>17 have any import or relevance to your opinions?</p> <p>18 A. What this says is that the obturator</p> <p>19 market will become a larger share of the</p> <p>20 midurethral sling market and because there are many</p> <p>21 competitors, it might be difficult to get customers</p> <p>22 back.</p> <p>23 Q. Are there any other slides in this</p> <p>24 exhibit that are relevant to your opinions?</p>	<p>1 The retropubic, see where it says</p> <p>2 "Retropubic," if I describe that as one sandbox and</p> <p>3 the obturator as another sandbox and the mini-sling</p> <p>4 as a third sandbox, does that make sense to you?</p> <p>5 MR. SNELL: Objection; form, leading.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Whether it's a sandbox or a category</p> <p>8 or --</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Three different categories.</p> <p>11 What were the three different</p> <p>12 categories -- what were the three different</p> <p>13 categories of products or future products that are</p> <p>14 being described here?</p> <p>15 A. There were -- was the retropubic</p> <p>16 category, the transobturator category and the</p> <p>17 mini-sling or single-incision sling category, which</p> <p>18 the Secur fell under.</p> <p>19 Q. And based on your review of this</p> <p>20 document and the documents -- internal documents,</p> <p>21 do you have an opinion as to whether or not Ethicon</p> <p>22 was attempting to maintain its market share by</p> <p>23 developing the third category of retro -- of</p> <p>24 midurethral slings in order to preserve its market</p>
Page 207	Page 209
<p>1 A. The next slide, which shows without the</p> <p>2 TVT-Secur what would -- is projected to happen to</p> <p>3 Gynecare's, which is a division of Ethicon's,</p> <p>4 market share, again, with the same tag bubble that</p> <p>5 we saw before.</p> <p>6 The next slide is a projection --</p> <p>7 Q. And do you have an understanding of what</p> <p>8 was expected to happen to Gynecare market share</p> <p>9 without the TVT-Secur?</p> <p>10 A. Yes, it was projected to decrease as</p> <p>11 what's seen in this slide.</p> <p>12 Q. And is there any other relevant slides</p> <p>13 that you want to discuss concerning your opinions?</p> <p>14 A. Yes. The next slide is a projection</p> <p>15 of -- with the single-incision or mini-sling or</p> <p>16 TVT-Secur, that Ethicon would grow that market and</p> <p>17 be the major -- have the -- the major share in that</p> <p>18 market.</p> <p>19 Q. And so -- and just want to understand</p> <p>20 some terminology a little bit.</p> <p>21 Are there sort of three or -- three</p> <p>22 different segments of the midurethral sling</p> <p>23 segment? Does that make sense? Maybe I should ask</p> <p>24 that in a better way.</p>	<p>1 share?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Have you seen Ethicon refer to these</p> <p>7 three different categories as sandboxes?</p> <p>8 MR. SNELL: Objection; leading.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes, I have in internal documents.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. So, when we talk about sandboxes later</p> <p>13 on and so that no one gets confused, we know that</p> <p>14 sandbox 1 would be the retropubic midurethral sling</p> <p>15 products, sandbox 2 would be the obturator sling</p> <p>16 products and sandbox 3 would be the mini-slugs.</p> <p>17 Is that fair?</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: Objection; leading.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Since I got a leading objection.</p> <p>22 How did some of Ethicon's employees</p> <p>23 describe these three different categories?</p> <p>24 A. As three different sandboxes.</p>

Bruce Alan Rosenzweig, M.D.

Page 210	Page 212
<p>1 Q. Are there any other relevant slides that</p> <p>2 you'd like to discuss that support your opinions?</p> <p>3 A. Yes. There's a summary slide that</p> <p>4 describes the need for the TVT-Secur to reclaim</p> <p>5 market share and to protect revenue.</p> <p>6 Q. Is that the slide that says "Summary"</p> <p>7 right there?</p> <p>8 A. Yes.</p> <p>9 Q. And these slides aren't numbered so for</p> <p>10 the record it says "Summary" and has two boxes,</p> <p>11 "The TVT-Secur reclaims our market share," and "The</p> <p>12 TVT-Secur protects our revenue," is that correct?</p> <p>13 MR. SNELL: Objection; leading.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. I think it's Slide No. 8.</p> <p>16 A. Yes.</p> <p>17 Q. And are there any other slides that</p> <p>18 support your opinion?</p> <p>19 A. Yes. "Unmet Needs." The next slide</p> <p>20 after that is called "Needs" for the TVT-Secur.</p> <p>21 Next slide, please. Is -- one of the needs is</p> <p>22 "Maximum safety."</p> <p>23 Q. And is it important for companies -- do</p> <p>24 you have an opinion whether or not it's important</p>	<p>1 less material that would be left behind in the</p> <p>2 patient?</p> <p>3 A. At the time of implant or throughout the</p> <p>4 rest of a woman's life?</p> <p>5 Q. Well, what matters the most?</p> <p>6 A. Throughout the rest of a woman's life.</p> <p>7 Q. So, do you have an opinion whether or</p> <p>8 not the TVT-Secur, mini-sling, offered patients a</p> <p>9 synthetic polypropylene material that would result</p> <p>10 in less material being left behind in the patient?</p> <p>11 A. Well, when we look at the success rate</p> <p>12 of the mini-sling, it is -- has design</p> <p>13 characteristics that make it unreasonably not</p> <p>14 effective and, therefore, they would have a</p> <p>15 recurrence of their stress incontinence and,</p> <p>16 therefore, would have the risk of having another</p> <p>17 polypropylene sling placed that would make it that</p> <p>18 they had even more polypropylene left behind.</p> <p>19 Q. So --</p> <p>20 MR. SNELL: Objection. Move to strike,</p> <p>21 non-responsive.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. So, what's the basis -- what's the</p> <p>24 support or basis for that opinion, Doctor?</p>
Page 211	Page 213
<p>1 for companies to maximize safety?</p> <p>2 A. Yes, it is important. It's important</p> <p>3 for patients to have the devices that are going to</p> <p>4 be permanently implanted in them to have</p> <p>5 characteristics that maximize safety and maximize</p> <p>6 efficacy.</p> <p>7 Q. Now, I want to talk to you real briefly</p> <p>8 about the third bullet point that says, "Less</p> <p>9 material left behind in the patient." Do you see</p> <p>10 that?</p> <p>11 A. Yes.</p> <p>12 Q. Isn't it true, Doctor, that if you</p> <p>13 create a mini-sling, a shorter sling, that you're</p> <p>14 leaving less foreign body, less synthetic material</p> <p>15 behind in a patient's body?</p> <p>16 MR. SNELL: Objection; leading.</p> <p>17 BY THE WITNESS:</p> <p>18 A. There would be the same amount of</p> <p>19 material in the vagina, but there will not be</p> <p>20 foreign material in areas where the sling is not.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Do you have an opinion whether or not</p> <p>23 Ethicon's mini-sling, the TVT-Secur, resulted in</p> <p>24 the implantation of less -- of a sling device with</p>	<p>1 A. The success rate for the mini-slugs.</p> <p>2 Q. Would it be accurate for Ethicon to</p> <p>3 represent to physicians or make a claim to</p> <p>4 physicians that if you used the TVT-Secur device,</p> <p>5 less foreign body material will be left behind in</p> <p>6 your patients? Would that be accurate?</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. It is not completely accurate because of</p> <p>10 the failure rate increases the risk of having</p> <p>11 another surgery to treat the recurrence or the</p> <p>12 continuation of incontinence, and that increases</p> <p>13 the risk of another midurethral sling being placed,</p> <p>14 which increases the risk or increases the amount of</p> <p>15 polypropylene that is left in their body.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. We are going to get to this in a little</p> <p>18 bit, but do you have an opinion about what the</p> <p>19 efficacy rate or the failure rate was for the</p> <p>20 TVT-Secur product?</p> <p>21 A. Well, there are some studies that show a</p> <p>22 better efficacy rate. There are many studies that</p> <p>23 show an accumulative efficacy rate of 75% or less.</p> <p>24 Q. And did you review any long-term studies</p>

54 (Pages 210 to 213)

Bruce Alan Rosenzweig, M.D.

Page 214	Page 216
<p>1 that looked at efficacy?</p> <p>2 A. Yes.</p> <p>3 Q. And what was the longest term study that</p> <p>4 you looked at regarding efficacy of the TVT-Secur</p> <p>5 product?</p> <p>6 A. Five years.</p> <p>7 Q. And what study was that?</p> <p>8 A. There are two. One is the Tommaselli</p> <p>9 study and one is the Haab study.</p> <p>10 Q. And did the -- how does or does the Haab</p> <p>11 study or how does the Haab study support, if at</p> <p>12 all, your opinion that patients who have the</p> <p>13 TVT-Secur device are at risk of having failure and</p> <p>14 more polypropylene material implanted to treat the</p> <p>15 failed procedure?</p> <p>16 MR. SNELL: Object; leading.</p> <p>17 BY THE WITNESS:</p> <p>18 A. The Haab study showed a 30% success rate</p> <p>19 after four and a half years and, therefore, those</p> <p>20 patients would be at risk for requiring another</p> <p>21 surgery to treat their recurrent stress urinary</p> <p>22 incontinence.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. So, a 30% success rate?</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No, they were not made to physicians.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Did Ethicon ever -- I'm just trying to</p> <p>6 understand this exhibit slide that says "Needs."</p> <p>7 It says the needs -- and they're talking about the</p> <p>8 third generation mini-slings, right?</p> <p>9 A. The third generation slings, yes.</p> <p>10 Q. Okay. And it says, "Needs. Maximize</p> <p>11 safety. Minimal passage through tissues. Less</p> <p>12 material left behind in the patient. No exit.</p> <p>13 Versatility," and then the last one says, "But same</p> <p>14 great efficacy."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. Do you know based on your review of</p> <p>18 Ethicon's internal documents whether they had made</p> <p>19 the claim to physicians that the TVT-Secur would</p> <p>20 have the same or equivalent efficacy as its other</p> <p>21 TVT first and second generation products?</p> <p>22 MR. SNELL: Object. Go ahead.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes, they did.</p>
Page 215	Page 217
<p>1 A. 30% success rate.</p> <p>2 Q. So, what's that failure rate?</p> <p>3 A. 70%.</p> <p>4 Q. So, does that mean -- what does that</p> <p>5 mean if we're talking about real patients? If</p> <p>6 there are ten patients who were going to undergo a</p> <p>7 procedure to put the TVT-Secur device in their</p> <p>8 bodies, how many of those ten patients were at risk</p> <p>9 of suffering a failure if they underwent TVT-Secur</p> <p>10 surgery?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Seven.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. So, seven out of ten?</p> <p>16 A. Correct.</p> <p>17 Q. And how many of those patients were at</p> <p>18 risk of having to undergo a second operation to</p> <p>19 implant more synthetic material to treat their</p> <p>20 stress urinary incontinence?</p> <p>21 A. Potentially seven out of ten.</p> <p>22 Q. So, we have these "Needs" here, and are</p> <p>23 these claims that Ethicon are making or made to</p> <p>24 physicians, do you know?</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And was that claim correct?</p> <p>3 A. No, it was not.</p> <p>4 Q. And what's the basis for your opinion?</p> <p>5 A. The review of the literature.</p> <p>6 Q. Are there any other slides you'd like to</p> <p>7 discuss with respect to Exhibit P04 -- 0842 that</p> <p>8 you believe support your opinions?</p> <p>9 A. The "Testing to Date."</p> <p>10 MR. THORNBURGH: And what slide is this, Tom,</p> <p>11 for the record? So people could find it.</p> <p>12 MR. BODYZIAK: I believe it's 16.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Slide 16. It says "Testing to Date" at</p> <p>15 the top?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And how does this slide support</p> <p>18 your opinions, if at all?</p> <p>19 A. This supports my opinions that the</p> <p>20 TVT-Secur was not adequately tested prior to</p> <p>21 launch.</p> <p>22 It describes that there was an animal</p> <p>23 study which only looked at pull-out forces, an</p> <p>24 animal histology study which looked at the size of</p>

55 (Pages 214 to 217)

Bruce Alan Rosenzweig, M.D.

Page 218	Page 220
<p>1 the anchors and the pull-out force of the anchors, 2 cadaver labs, an infection analysis, a second 3 animal study was underway and there was some 4 testing between mechanical-cut and laser-cut -- 5 laser cutting that was underway at the time of this 6 PowerPoint presentation. 7 Q. Okay. And Tom has the slide pulled up 8 real quick, but I just want to ask really quick. 9 The first two bullet points that say 10 "Animal - Pull out force studies, Animal histology 11 studies," was that the first animal study that you 12 had discussed earlier? 13 A. Yes. 14 Q. And that was -- what product did that 15 study test? 16 MR. SNELL: Object. 17 BY THE WITNESS: 18 A. The TVT X, which was 12 centimeters and 19 did not have the final embodiment of the fleece 20 ends that ultimately are in the TVT-Secur. 21 BY MR. THORNBURGH: 22 Q. Would it be appropriate, do you have an 23 opinion -- strike that. 24 Do you have an opinion whether or not it</p>	<p>1 Q. Is this the same design validation 2 studies -- are you aware whether or not this is the 3 same design validation studies that Mark Yale wrote 4 about being concerned that there was a steaming 5 pile of blank? 6 A. Yes. 7 MR. SNELL: Objection. 8 BY MR. THORNBURGH: 9 Q. Did the cadaveric lab, any cadaveric 10 lab, including the labs that were done in the 11 design validation phase, did any of those support 12 the safety and efficacy of the TVT-Secur product? 13 A. No. 14 Q. The next bullet point says, "Infection 15 risk analysis." Are you aware of that study? 16 A. I recall seeing the data from that. 17 Q. Did the infection risk analysis support 18 the safety or efficacy of the TVT-Secur product as 19 for treatment of stress urinary incontinence in 20 live human women? 21 A. No. 22 Q. Why is that? 23 A. It was not done in live human women. 24 Q. Was it done in animals, an animal?</p>
Page 219	Page 221
<p>1 would be appropriate for Ethicon to represent to 2 the world or to physicians that the TVT X studies 3 or the results from the TVT X studies supported the 4 efficacy or safety of the TVT-Secur product? 5 MR. SNELL: Object. 6 BY THE WITNESS: 7 A. I do have an opinion. 8 BY MR. THORNBURGH: 9 Q. What's that opinion? 10 A. It does not support the safety and 11 efficacy of the TVT-Secur. 12 Q. Was the TVT X even the same product at 13 all? 14 A. No. 15 Q. The next -- third bullet point says, 16 "9 cadaveric labs (sizing/pull out)." 17 Do you see that? 18 A. Yes. 19 Q. Is this the design validation studies 20 that you discussed earlier with the jury? 21 A. Yes. 22 Q. Is this the same design validation 23 studies -- 24 A. Well -- yes, yes.</p>	<p>1 A. It was done in a laboratory setting. 2 Q. And the next bullet point says, "Second 3 animal study underway." 4 Are you aware what animal study that 5 was? 6 A. A -- if I recall, that was another sheep 7 cadaver study. 8 Q. And did the second sheep cadaver study 9 support the safety or efficacy of the TVT-Secur 10 product for permanent implantation in women? 11 A. No. 12 Q. The last bullet point says, "Laser 13 versus mechanical testing underway." 14 Did any of the laser versus mechanical 15 testing support the safety of the TVT-Secur as a 16 permanent implant in the female woman -- female 17 body? 18 A. No. 19 Q. What's the next slide in your 20 presentation that you want to discuss? 21 A. The slide of the competitor mini-slugs 22 that were either launched or proposed to be 23 launched in the near future. 24 Q. And do you have an understanding as to</p>

Bruce Alan Rosenzweig, M.D.

Page 222	Page 224
<p>1 whether or not these were some of the competitors 2 of Ethicon? 3 A. Yes. 4 Q. What's the next slide you'd like to 5 discuss? 6 A. The "Product Strategy." 7 Q. Okay. And it's a slide called "Product 8 Strategy," and how does this document support your 9 opinions, if at all? 10 A. Well, it shows that the last phase of 11 their product strategy is obtaining clinical data, 12 and that supports my opinion that the TVT-Secur 13 device was not adequately tested prior to launch. 14 Q. Wait. Now, hold on a second. Let's 15 look at these phases really quickly, okay. 16 What was Phase 1 for Ethicon's product 17 strategy concerning the TVT-Secur device? 18 A. Actively convert the obturator users, 19 also approach the low hanging retropubic users. 20 Q. So, would Phase 1 occur after launch of 21 the product? 22 A. Yes. 23 Q. What about Phase 2, would that be after 24 launch of the product?</p>	<p>1 Q. And would Phase 3 occur after the 2 TVT-Secur was launched on the market? 3 A. Yes. 4 Q. Doctor, have you ever heard of the 5 acronym R & D? 6 A. Yes. 7 Q. What does R & D stand for, Doctor? 8 A. Research and development. 9 Q. Based on your knowledge, training and 10 experience, your review of these company documents 11 and the peer-reviewed publications, do you have an 12 opinion whether or not a company should research 13 products before they develop and launch products as 14 permanent implant devices for human use? 15 MR. SNELL: Object. 16 BY THE WITNESS: 17 A. Products should be researched prior to 18 launch for human use. 19 BY MR. THORNBURGH: 20 Q. Did Ethicon appropriately research the 21 TVT-Secur product before they launched it on to the 22 market? 23 MR. SNELL: Object. 24 BY THE WITNESS:</p>
Page 223	Page 225
<p>1 A. Yes. 2 Q. And what was Phase 2? 3 A. Convert the remaining of the obturator 4 users and actively convert all retropubic users. 5 Q. Now, was Phase 3 also after the launch 6 of the product? 7 A. Yes. 8 Q. So, hold on a second. 9 Ethicon has, "Protect market share 10 through Key Opinion Leaders, KOLs, and clinical 11 data." That was their third phase. Am I reading 12 that correctly? 13 MR. SNELL: Objection; leading. 14 BY THE WITNESS: 15 A. Yes. 16 BY MR. THORNBURGH: 17 Q. Let me rephrase because I got an 18 objection. 19 Phase 3 was to protect market share 20 through KOLs and clinical data, is that correct? 21 MR. SNELL: Leading. 22 BY THE WITNESS: 23 A. Yes. 24 BY MR. THORNBURGH:</p>	<p>1 A. No, they did not. There was not 2 appropriate testing prior to launch. 3 BY MR. THORNBURGH: 4 Q. Because I got an objection, let me 5 reask. 6 Because -- do you have an opinion 7 whether or not Ethicon appropriately researched its 8 product, the TVT-Secur, before they launched it? 9 A. Yes, I have an opinion. 10 MR. SNELL: Objection. 11 BY MR. THORNBURGH: 12 Q. What's that opinion? 13 MR. SNELL: Same objection. Go ahead. 14 BY THE WITNESS: 15 A. It was not appropriately researched or 16 tested prior to launch. 17 BY MR. THORNBURGH: 18 Q. In your opinion is it ever appropriate 19 for companies such as Ethicon who are selling 20 patients permanent implantable medical devices to 21 develop and market products before they conduct the 22 appropriate research? 23 MR. SNELL: Object. 24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 226	Page 228
<p>1 A. No, that is never appropriate.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Is it appropriate for companies to put</p> <p>4 the D before the R --</p> <p>5 MR. SNELL: Object.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. -- in R & D?</p> <p>8 MR. SNELL: Object: Leading as well.</p> <p>9 BY THE WITNESS:</p> <p>10 A. It is not appropriate to launch a</p> <p>11 product without it being adequately tested.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Do you have an opinion whether or not</p> <p>14 the conduct of Ethicon in developing this product</p> <p>15 strategy was appropriate?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. It was not appropriate.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Do you have an opinion whether or not</p> <p>21 conducting business in this manner places women at</p> <p>22 risk of suffering harm or injuries?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>	<p>1 that had never been used before should dedicate</p> <p>2 some of its budget pre-launch to testing their</p> <p>3 products and conducting adequate testing of their</p> <p>4 products in humans?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes. The product should be adequately</p> <p>8 tested prior to launch and adequate budget should</p> <p>9 be set aside to conduct testing prior to launch.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Do you have an opinion whether or not</p> <p>12 medical device companies should budget more</p> <p>13 money -- more money to conducting randomized</p> <p>14 controlled trials or adequate testing than they do</p> <p>15 in marketing?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What's that opinion?</p> <p>21 A. That they should allocate more money for</p> <p>22 adequately testing a product prior to launch than</p> <p>23 they should allocate towards marketing.</p> <p>24 Q. Have you reviewed any internal Ethicon</p>
Page 227	Page 229
<p>1 A. Yes, it puts women at risk of harm and</p> <p>2 injury.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Is there another slide you'd like to</p> <p>5 discuss with us?</p> <p>6 A. Yes. Pre-launch marketing budget for</p> <p>7 2005.</p> <p>8 Q. Try to find it, Doctor.</p> <p>9 And what is the significance of this</p> <p>10 slide, Doctor?</p> <p>11 A. Well, it supports my opinion that there</p> <p>12 was no clinical testing prior to launch of the</p> <p>13 TVT-Secur.</p> <p>14 Q. Now, let's look at this. It says,</p> <p>15 "Gynecare TVT-Secur Pre-Launch Marketing 2005</p> <p>16 Budget."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 Q. How much, according to this budget, did</p> <p>20 Ethicon budget for developing or for conducting</p> <p>21 randomized controlled trials?</p> <p>22 A. Zero.</p> <p>23 Q. Do you have an opinion whether or not a</p> <p>24 company who is selling a new device and technique</p>	<p>1 documents that discuss a reason why randomized</p> <p>2 controlled trials were not conducted by Ethicon?</p> <p>3 MR. SNELL: Object; leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what is your opinion as to why</p> <p>8 Ethicon chose not to conduct randomized controlled</p> <p>9 trials prior to launching the TVT-Secur product?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Budget constraints.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Based on your review of this slide, the</p> <p>15 pre-launch marketing 2005 budget, with a total</p> <p>16 budget of 80 -- \$800 million, is there any</p> <p>17 indication that Johnson & Johnson or Ethicon did</p> <p>18 not have enough money to conduct adequate testing?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That would not appear that way from that</p> <p>22 slide.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Are there any other slides you'd like to</p>

Bruce Alan Rosenzweig, M.D.

Page 230	Page 232
<p>1 discuss with respect to Exhibit P842?</p> <p>2 A. Yes. It's called "Potential Marketing</p> <p>3 Claims."</p> <p>4 Q. And what, if anything, is relevant with</p> <p>5 this slide and how does it support your opinions?</p> <p>6 A. This is a slide of what they will be</p> <p>7 claiming as a TVT-Secur device. They would --</p> <p>8 wanted to claim that it had the same equivalence as</p> <p>9 the TVT. The data show that it was not equivalent</p> <p>10 to the TVT.</p> <p>11 That the length was acceptable to all</p> <p>12 patients. The 8 centimeter length did not stay in</p> <p>13 place in all patients and therefore the failure</p> <p>14 rate was high.</p> <p>15 They wanted to claim that laser-cut mesh</p> <p>16 was the same as the mechanical-cut mesh. However,</p> <p>17 the laser-cut mesh was found to be three times</p> <p>18 stiffer than mechanical-cut laser and stiffness</p> <p>19 leads to the harms that I've described previously.</p> <p>20 Q. What's your basis for that last</p> <p>21 statement, that the stiffness or rigidity of a mesh</p> <p>22 leads to harms that you've described previously?</p> <p>23 A. The medical literature.</p> <p>24 MR. SNELL: Objection. I'm sorry. Object and</p>	<p>1 make certain marketing claims that they wouldn't</p> <p>2 prove until they conducted later clinical trials?</p> <p>3 MR. SNELL: Object and leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. That's what this document states.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. What does this document and the red and</p> <p>8 black font indicate to you and how does it support</p> <p>9 your opinions?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. The red font is claims that would be</p> <p>13 later proven from either clinical data or clinical</p> <p>14 experience. Therefore, that supports my opinion</p> <p>15 that the TVT-Secur was not adequately studied prior</p> <p>16 to launch.</p> <p>17 Q. Is it -- in your opinion, is it ever</p> <p>18 appropriate for a company to make marketing claims</p> <p>19 that are unproven?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. That should not be done.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. And what can happen if companies like</p>
Page 231	Page 233
<p>1 move to strike as non-responsive.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And we'll talk about those in greater</p> <p>4 detail. But what medical literature are you</p> <p>5 referring to?</p> <p>6 A. The work done by the Feola group in</p> <p>7 Pittsburgh. Excuse me. The Moalli group in</p> <p>8 Pittsburgh.</p> <p>9 Q. And this slide -- and I didn't mean to</p> <p>10 interrupt you. If you weren't done, keep on going,</p> <p>11 Doctor.</p> <p>12 A. No. I'm finished with this.</p> <p>13 Q. And this particular slide shows</p> <p>14 potential marketing claims and there are a number</p> <p>15 of bullets, some of which are in black font, some</p> <p>16 of which are in red font, and there is a double</p> <p>17 asterisk. What does that double asterisk indicate?</p> <p>18 A. Well, it indicates what the potential</p> <p>19 marketing claims in red signify, and what that</p> <p>20 signifies is that this will be found on later</p> <p>21 clinical trials.</p> <p>22 Q. So, hold on a second. Trying to</p> <p>23 understand this.</p> <p>24 Does this indicate that Ethicon would</p>	<p>1 Ethicon make unproven marketing claims?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. That women will have the device</p> <p>5 implanted that have design characteristics that</p> <p>6 make it either unreasonably unsafe or unreasonably</p> <p>7 ineffective and will suffer harm from that.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Is it -- are there any -- any more</p> <p>10 slides or data or information from this Exhibit</p> <p>11 No. 842 that support your opinions that you want to</p> <p>12 discuss today?</p> <p>13 A. No.</p> <p>14 Q. What's the next slide that you want to</p> <p>15 discuss?</p> <p>16 A. This is a brochure that the marketing</p> <p>17 people, particularly if I recall the ones that came</p> <p>18 to my office, presented regarding the TVT-Secur.</p> <p>19 Q. Doctor, is it reasonable for physicians</p> <p>20 who are trying to make treatment options or</p> <p>21 navigate the treatment options available to their</p> <p>22 patients to rely on the marketing claims of medical</p> <p>23 device companies?</p> <p>24 MR. SNELL: Objection.</p>

59 (Pages 230 to 233)

Bruce Alan Rosenzweig, M.D.

Page 234	Page 236
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Let me ask it a better way.</p> <p>3 Is it unreasonable for medical doctors</p> <p>4 to rely on the marketing claims made by medical</p> <p>5 device companies like Ethicon who are promoting</p> <p>6 medical devices for the permanent implantation into</p> <p>7 patients?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Is it unreasonable to rely on company</p> <p>11 representations about their devices?</p> <p>12 MR. SNELL: Same.</p> <p>13 BY THE WITNESS:</p> <p>14 A. It is not unreasonable to rely on claims</p> <p>15 that are made by the company.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Do you have an opinion whether or not</p> <p>18 medical device companies like Ethicon and</p> <p>19 Johnson & Johnson should not only disclose the</p> <p>20 benefits of their products, but also safety or</p> <p>21 efficacy problems with their products?</p> <p>22 A. Yes.</p> <p>23 Q. And why is that important?</p> <p>24 A. It is important so that doctors know all</p>	<p>1 Q. Is that a method used by the medical</p> <p>2 community when determining what treatment options</p> <p>3 would be appropriate for their patients, one of the</p> <p>4 methods?</p> <p>5 MR. SNELL: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And is it important -- do you have an</p> <p>10 opinion whether or not it's important that doctors</p> <p>11 are provided with the complete and accurate</p> <p>12 information concerning the risks as well as the</p> <p>13 complete and accurate information concerning</p> <p>14 benefits?</p> <p>15 A. Yes.</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. If -- if medical device companies like</p> <p>19 Ethicon and Johnson & Johnson do not provide</p> <p>20 complete and accurate information concerning both</p> <p>21 the risks and the benefits of medical devices that</p> <p>22 they're promoting, can that impact patient safety?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>
Page 235	Page 237
<p>1 of the risks associated with the device so the</p> <p>2 doctor can make a decision whether or not they will</p> <p>3 use that device in their patients so they can give</p> <p>4 that information to the patients so the patient can</p> <p>5 ultimately make an informed decision about their</p> <p>6 treatment.</p> <p>7 Q. How do doctors make a decision about</p> <p>8 treatment options for their patients?</p> <p>9 MR. SNELL: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Based on information that is provided by</p> <p>12 the manufacturer, what's in the literature, and</p> <p>13 from their clinical experience.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. I've heard the phrase before</p> <p>16 "risk/benefit assessment." Have you heard -- am I</p> <p>17 using that phrase correctly?</p> <p>18 A. Yes.</p> <p>19 Q. Doctor, what is a risk/benefit</p> <p>20 assessment?</p> <p>21 A. It is an assessment that is made where</p> <p>22 the risks associated with an individual device,</p> <p>23 procedure or treatment is weighed against the</p> <p>24 utility or benefits to the patient.</p>	<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Can that impact the decision-making</p> <p>4 process of physicians?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. How so?</p> <p>10 A. If all the information regarding the</p> <p>11 characteristics of a device that make it</p> <p>12 unreasonably unsafe or unreasonably ineffective are</p> <p>13 not shared with doctors, doctors cannot make an</p> <p>14 accurate risk/benefit analysis and have a proper</p> <p>15 risk discussion with their patients.</p> <p>16 Q. Okay. And let's discuss Exhibit P1352.</p> <p>17 Did you review and rely on this document in</p> <p>18 rendering your opinions in this case?</p> <p>19 A. Yes.</p> <p>20 Q. And I think you testified earlier that</p> <p>21 you had seen this document before you were retained</p> <p>22 as an expert in this litigation?</p> <p>23 A. Yes.</p> <p>24 Q. Is it fair to say that of all the</p>

60 (Pages 234 to 237)

Bruce Alan Rosenzweig, M.D.

Page 238	Page 240
<p>1 documents we've looked at so far, internal company</p> <p>2 documents, other than this document and the</p> <p>3 TVT-Secur IFU that we looked at earlier, were any</p> <p>4 of those other documents disclosed to you or to the</p> <p>5 medical community?</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Not that I recall.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Okay. And what about Exhibit 1352 is</p> <p>11 relevant to your opinions? And if you could</p> <p>12 explain briefly how this information or what</p> <p>13 information you rely on to support those opinions.</p> <p>14 A. I rely on -- relied on the entire</p> <p>15 document to support my opinions that the TVT-Secur</p> <p>16 data -- there was no data on the TVT-Secur at the</p> <p>17 time of launch.</p> <p>18 Therefore, these brochures that talk</p> <p>19 about a 97% overall success rate, that it had</p> <p>20 been -- that there was a low complication rate and</p> <p>21 that it had been in over a million -- used in over</p> <p>22 a million women worldwide and that there is</p> <p>23 seven-year proven efficacy, is not data that is</p> <p>24 applicable to the TVT-Secur.</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Do you agree or disagree with</p> <p>6 Dr. Arnaud?</p> <p>7 A. I --</p> <p>8 MR. SNELL: Same.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I agree with Dr. Arnaud that it is not a</p> <p>11 revolution.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. What's the next part of Exhibit P1352</p> <p>14 that is relevant and that you rely on for your</p> <p>15 opinions?</p> <p>16 A. The statement that it is less</p> <p>17 complicated.</p> <p>18 Q. And how does that support your opinion?</p> <p>19 A. This statements that the TVT-Secur is</p> <p>20 designed to reduce the number of procedural steps.</p> <p>21 From the cadaver studies and the design validation,</p> <p>22 it was found to be more complicated to insert with</p> <p>23 more difficulty inserting than the prior TVT</p> <p>24 devices.</p>
Page 239	Page 241
<p>1 Q. Okay.</p> <p>2 MR. SNELL: Objection. Move to strike.</p> <p>3 Non-responsive.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Okay. And this document, the very</p> <p>6 first -- the title of this promotional piece says</p> <p>7 "No bigger than your palm. No less than a</p> <p>8 revolution."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Did you read the deposition testimony of</p> <p>12 Axel Arnaud?</p> <p>13 A. Yes.</p> <p>14 Q. Do you know whether or not based on your</p> <p>15 review of Axel Arnaud's testimony -- and before we</p> <p>16 get there. So, strike the last question.</p> <p>17 Who is Dr. Axel Arnaud?</p> <p>18 A. One of the Medical Directors at Ethicon.</p> <p>19 Q. Do you know whether or not Dr. Axel</p> <p>20 Arnaud agreed or disagreed that the TVT-Secur was a</p> <p>21 revolution?</p> <p>22 A. He disagreed.</p> <p>23 Q. Now, if we look at -- and do you agree</p> <p>24 with Dr. Arnaud?</p>	<p>1 Q. So, is this statement by Ethicon that</p> <p>2 the TVT-Secur was less complicated true or</p> <p>3 incorrect?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Incorrect.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And what's the support for that opinion?</p> <p>9 A. The design validation which showed that</p> <p>10 it was much more complicated to put in.</p> <p>11 Q. If we look at -- strike that.</p> <p>12 What is the next relevant information</p> <p>13 you'd like to discuss?</p> <p>14 A. The next page, the "Novel Instrument</p> <p>15 Design, Stable." The absorbable fleece tips</p> <p>16 provide mechanical fixation until tissue ingrowth</p> <p>17 can occur.</p> <p>18 The fleece tips were shown by the</p> <p>19 literature not to hold, which allowed the mesh to</p> <p>20 move and migrate, which decreased the efficacy of</p> <p>21 the procedure and increased the harm, such as</p> <p>22 erosion and pain.</p> <p>23 Q. So, is this an incorrect or correct</p> <p>24 statement by Ethicon that the TVT-Secur was indeed</p>

Bruce Alan Rosenzweig, M.D.

Page 242	Page 244
<p>1 or in fact secure?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Incorrect.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Do you have an opinion whether or not it</p> <p>7 would be a misrepresentation for Ethicon to</p> <p>8 represent to physicians that the TVT-Secur was</p> <p>9 secure and would stay in place?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. I do have an opinion.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. What's that opinion?</p> <p>15 A. That that would be a misrepresentation.</p> <p>16 Q. And by -- by marketing this product and</p> <p>17 naming it the TVT-Secur, is that -- do you have an</p> <p>18 opinion whether or not the name that Ethicon gave</p> <p>19 it was a misrepresentation?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yes, I have an opinion.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. What's that opinion?</p>	<p>1 Q. What's the basis for that opinion?</p> <p>2 A. Based on the design validation cadaver</p> <p>3 studies.</p> <p>4 Q. And did Ethicon conduct any human</p> <p>5 studies before they launched it that suggested that</p> <p>6 the TVT-Secur would not -- would or would not be</p> <p>7 effective?</p> <p>8 A. Yes. The five-week data on 31 patients</p> <p>9 which showed a failure rate of 30%.</p> <p>10 Q. The next -- what's the next page that</p> <p>11 you'd like to discuss?</p> <p>12 A. "Innovative tension-free fixation</p> <p>13 technology keeps the mesh in place."</p> <p>14 Q. We haven't really talked about this. I</p> <p>15 think we brought it up just briefly during the</p> <p>16 implant training video.</p> <p>17 But what does it mean to be</p> <p>18 tension-free?</p> <p>19 A. There is no accurate way to describe the</p> <p>20 amount of tension that should be placed on a</p> <p>21 midurethral sling during the implantation.</p> <p>22 Q. And if we look at the TVT-Secur box</p> <p>23 really quick, the box that the TVT-Secur came in.</p> <p>24 Hold that up for the ladies and</p>
Page 243	Page 245
<p>1 A. It was a misrepresentation.</p> <p>2 Q. And what's the basis for that opinion?</p> <p>3 MR. SNELL: Same.</p> <p>4 BY THE WITNESS:</p> <p>5 A. The literature.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Did Ethicon know or should they have</p> <p>8 known based on your review of the internal company</p> <p>9 documents by 2006 when they launched this product</p> <p>10 that the TVT-Secur was a more complicated</p> <p>11 procedure?</p> <p>12 MR. SNELL: Objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Than the TVT-O or TVT Retropubic?</p> <p>17 A. Yes.</p> <p>18 Q. Did Ethicon know before they launched</p> <p>19 the TVT-Secur in September of 2006 that the mesh</p> <p>20 would not stay in place?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yes.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 gentlemen of the jury.</p> <p>2 THE VIDEOGRAPHER: Let me focus. Hold on.</p> <p>3 Okay. I got it.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And what were you showing the ladies and</p> <p>6 gentlemen of the jury?</p> <p>7 A. It says, "Tension-free support for</p> <p>8 incontinence."</p> <p>9 Q. Was it an accurate statement or</p> <p>10 representation that the Gynecare TVT-Secur system</p> <p>11 was tension-free support for incontinence?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Inaccurate.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And what's the basis for that opinion?</p> <p>17 A. The internal documents and the</p> <p>18 literature.</p> <p>19 Q. And did Ethicon know before they</p> <p>20 marketed and sold this product that it would be a</p> <p>21 misrepresentation to claim that the Gynecare</p> <p>22 TVT-Secur system was tension-free support for</p> <p>23 incontinence?</p> <p>24 MR. SNELL: Object.</p>

62 (Pages 242 to 245)

Bruce Alan Rosenzweig, M.D.

Page 246	Page 248
<p>1 BY THE WITNESS:</p> <p>2 A. They should have known, yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And what's the next page you'd like to</p> <p>5 discuss?</p> <p>6 A. The "Materials, Dependable, Reliable."</p> <p>7 Q. Do you have an opinion whether or not --</p> <p>8 strike that.</p> <p>9 How does these statements by Ethicon</p> <p>10 that the TVT-Secur is dependable and reliable</p> <p>11 support your opinions?</p> <p>12 A. Well, the Prolene mesh in the short</p> <p>13 length with laser cutting had never been used</p> <p>14 before so, therefore, it could not be known to be</p> <p>15 dependable because it had not been studied in</p> <p>16 the -- in the humans prior to launch except in 31</p> <p>17 women for five weeks.</p> <p>18 The reliability of the fleece tips had</p> <p>19 never been used before in women. The only data</p> <p>20 that they had was on 31 women for five weeks. So,</p> <p>21 to be able to say that the short mesh with</p> <p>22 laser-cut and the fleece tips were dependable and</p> <p>23 reliable, the only human data was on 31 women for</p> <p>24 five weeks.</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. We had just looked at some claims</p> <p>3 that -- that -- a moment ago we looked at</p> <p>4 Exhibit 842 for some claims that Ethicon would use</p> <p>5 to market the TVT-Secur product. Do you recall</p> <p>6 that?</p> <p>7 A. Yes.</p> <p>8 Q. And I want to first go to a side-by-side</p> <p>9 of this statement or this data that is reflected in</p> <p>10 the promotional piece of Exhibit 1352 and compare</p> <p>11 it to the claims that Ethicon wanted to make with</p> <p>12 respect to the TVT-Secur system.</p> <p>13 MR. SNELL: Object.</p> <p>14 MR. THORNBURGH: And what slide is that again,</p> <p>15 Tom? Could you just pull it up.</p> <p>16 MR. BODYZIAK: It's the last one. So, it's --</p> <p>17 MR. THORNBURGH: The last slide of</p> <p>18 Exhibit P842.</p> <p>19 MR. BODYZIAK: Slide 40, page 41 of the</p> <p>20 document.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And you'll see, again, we looked at this</p> <p>23 earlier, but it says red would be "Later from</p> <p>24 clinicals."</p>
Page 247	Page 249
<p>1 Q. And did the human data on 31 women for</p> <p>2 five weeks, did that demonstrate or prove that the</p> <p>3 TVT-Secur would be dependable?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. No, there is a failure rate of 30%.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Did it prove or demonstrate that the</p> <p>9 TVT-Secur would be reliable?</p> <p>10 A. No, there was a 60% complication rate.</p> <p>11 Q. What is the next --</p> <p>12 MR. SNELL: Object. Move to strike.</p> <p>13 Nonresponsive. Go ahead.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What is the next -- is there any other</p> <p>16 information you'd like to discuss from</p> <p>17 Exhibit P1352?</p> <p>18 A. Yes. The next page, which describes the</p> <p>19 seven-year data. We've already seen e-mail</p> <p>20 statements from key Ethicon employees noting that</p> <p>21 the seven-year data would not be reliably</p> <p>22 translatable to the TVT-Secur.</p> <p>23 MR. SNELL: Object; misstates. Move to</p> <p>24 strike.</p>	<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And the claim that Ethicon was going to</p> <p>4 market to promote the TVT-Secur says, or one of the</p> <p>5 claims, is "Equivalent efficacy to TVT or TVT-O."</p> <p>6 Do you see that?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Based on Ethicon's own internal document</p> <p>12 from the potential marketing claims, was that claim</p> <p>13 proven or unproven?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Unproven.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And yet despite that, if we go and</p> <p>19 compare that to the -- the data that was being</p> <p>20 provided to doctors in P1352, what was Ethicon</p> <p>21 representing to physicians who were considering</p> <p>22 whether or not to implant the TVT-Secur permanently</p> <p>23 in their patients?</p> <p>24 A. That the --</p>

63 (Pages 246 to 249)

Bruce Alan Rosenzweig, M.D.

Page 250	Page 252
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. That the overall success rate was 97%.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Were they suggesting that the success</p> <p>6 rate of the TVT-Secur was equivalent to the</p> <p>7 efficacy of the TVT and TVT-O?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Was that a misrepresentation? Strike</p> <p>13 that.</p> <p>14 Do you have an opinion whether or not</p> <p>15 that was a true claim?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes, I have an opinion.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What's the opinion?</p> <p>21 MR. SNELL: Same.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That was not a true claim.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 marketing piece that this was an unproven claim?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, they did not.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Would it have been reasonable for</p> <p>7 physicians who were provided this marketing piece</p> <p>8 to believe based on the information Ethicon was</p> <p>9 providing to them that the TVT-Secur was as</p> <p>10 efficacious as the TVT Retropubic device?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. It would not be an unreasonable</p> <p>14 assumption.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Would it be reasonable for consumers to</p> <p>17 expect that the TVT-Secur would perform at least as</p> <p>18 well as the TVT Retropubic or TVT-Obturator</p> <p>19 devices?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Based on this brochure, one would --</p> <p>23 could make that assumption.</p> <p>24 BY MR. THORNBURGH:</p>
Page 251	Page 253
<p>1 Q. Do you have an opinion whether or not</p> <p>2 that was a proven claim?</p> <p>3 A. Yes, I have an opinion.</p> <p>4 MR. SNELL: Same objection.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. What's that opinion?</p> <p>7 A. That it was not a proven claim.</p> <p>8 Q. Do you have an opinion whether or not it</p> <p>9 was appropriate for Ethicon to represent to</p> <p>10 physicians that the TVT-Secur had equivalent</p> <p>11 efficacy or worked just as well as the TVT-Secur --</p> <p>12 TVT -- strike that. Let me reask because I messed</p> <p>13 up.</p> <p>14 Do you have an opinion whether or not it</p> <p>15 was appropriate for Ethicon to represent to</p> <p>16 physicians that the TVT-Secur was equivalent in</p> <p>17 efficacy as the TVT Retropubic or TVT-Obturator?</p> <p>18 MR. SNELL: Same objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes, I have an opinion.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What is that opinion?</p> <p>23 A. That that would be a misrepresentation.</p> <p>24 Q. Did Ethicon tell physicians in this</p>	<p>1 Q. Any other information that you'd like to</p> <p>2 discuss concerning the information in this exhibit,</p> <p>3 Exhibit P1352?</p> <p>4 A. The next page, it states, "Gynecare's</p> <p>5 commitment to evidence-based medicine, ongoing</p> <p>6 studies with the TVT-Secur, a post-market</p> <p>7 evaluation of 50 patients and a prospective</p> <p>8 multi-center study with 300 patients."</p> <p>9 Q. Based on your review of, in this case,</p> <p>10 of Ethicon's internal documents, was Gynecare</p> <p>11 committed to evidence-based medicine?</p> <p>12 A. They did not sponsor a prospective or</p> <p>13 they did not perform their own prospective</p> <p>14 randomized multi-center trial of 300 patients.</p> <p>15 MR. SNELL: Objection. Non-responsive. Move</p> <p>16 to strike.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Hold on a second. This is a marketing</p> <p>19 piece that Ethicon would use after the TVT-Secur</p> <p>20 was on the market?</p> <p>21 A. Correct.</p> <p>22 Q. After -- by the time Ethicon had brought</p> <p>23 the TVT-Secur to market and had begun to sell it,</p> <p>24 had they already looked at the interim data for</p>

64 (Pages 250 to 253)

Bruce Alan Rosenzweig, M.D.

Page 254	Page 256
<p>1 this first study that they discuss here under the</p> <p>2 statement that Gynecare was committed to</p> <p>3 evidence-based medicine?</p> <p>4 A. Yes.</p> <p>5 Q. And did the interim data that Ethicon</p> <p>6 reviewed from the First Human Use Study, did that</p> <p>7 demonstrate that the evidence supported the safety</p> <p>8 or efficacy of Ethicon's Secur product?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That study did not.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Is this statement something that would</p> <p>14 have been reasonable for doctors to rely on?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. It --</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Strike that. Let me ask a better</p> <p>20 question.</p> <p>21 Rather than tell doctors that you are as</p> <p>22 a company committed to evidence-based medicine,</p> <p>23 would it have been appropriate instead for Ethicon</p> <p>24 to disclose in this promotional piece the interim</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Do you have an opinion whether or not</p> <p>5 the data from the interim First Human Use Study</p> <p>6 would have -- would have been beneficial to</p> <p>7 implanting physicians when performing their</p> <p>8 risk/benefit assessment?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Why is that?</p> <p>14 MR. SNELL: Same.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Doctors need all the information</p> <p>17 available to them about the success and the</p> <p>18 complications associated with a medical device in</p> <p>19 order to make an accurate risk/benefit analysis to</p> <p>20 determine whether or not they would use a</p> <p>21 particular device to treat a particular condition.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Based on your review of Ethicon's</p> <p>24 internal company documents, did it ever edit this</p>
Page 255	Page 257
<p>1 data from the First Human Use Study?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. That would have been appropriate.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did they do that?</p> <p>7 MR. SNELL: Same.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No, they did not.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Could they have?</p> <p>12 MR. SNELL: Same.</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Should they have?</p> <p>16 MR. SNELL: Same objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What is the risk -- is there a risk of</p> <p>21 harm to patients if companies like Ethicon don't</p> <p>22 completely and accurately disclose the safety or</p> <p>23 efficacy information that they have?</p> <p>24 MR. SNELL: Object.</p>	<p>1 brochure that it provided to doctors?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, they did not.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did Ethicon ever edit this promotional</p> <p>7 marketing piece that it provided to doctors to</p> <p>8 disclose the interim data from the First Human Use</p> <p>9 Study?</p> <p>10 A. No, they did not.</p> <p>11 Q. Did Ethicon ever edit this brochure or</p> <p>12 provide an updated brochure or create a new</p> <p>13 brochure that disclosed to implanting physicians</p> <p>14 the final results from the 12 -- 12-month First</p> <p>15 Human Use Data Study?</p> <p>16 A. No, they did not.</p> <p>17 Q. Could they have?</p> <p>18 A. Yes.</p> <p>19 Q. Should they have?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Object.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. We are going to talk about the 12-month</p> <p>24 data here in a little bit, but what was the outcome</p>

65 (Pages 254 to 257)

Bruce Alan Rosenzweig, M.D.

Page 258	Page 260
<p>1 of that study?</p> <p>2 A. That the success rate was less than 70%</p> <p>3 and the complication rate was 60%.</p> <p>4 Q. Did that company -- did that 12-month</p> <p>5 study pass -- or strike that.</p> <p>6 Did that 12-month study support the</p> <p>7 safety or efficacy of the TVT-Secur product?</p> <p>8 A. No, it did not.</p> <p>9 Q. Did that study fail or pass, in other</p> <p>10 words, did the study results demonstrate safety and</p> <p>11 efficacy?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No, it did not.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Did the study fail to meet its primary</p> <p>17 endpoints for safety?</p> <p>18 A. Yes.</p> <p>19 Q. Did the study fail to meet its primary</p> <p>20 endpoints for efficacy?</p> <p>21 A. Yes.</p> <p>22 Q. Did Ethicon ever disclose that to any</p> <p>23 doctors in the community?</p> <p>24 A. No.</p>	<p>1 patients, and it -- the discussion shows that the</p> <p>2 interim data is not good. It showed the higher</p> <p>3 failure rate that was the primary endpoint. It</p> <p>4 also showed a higher complication rate.</p> <p>5 Q. Okay. So, let me try to dissect this a</p> <p>6 little bit.</p> <p>7 Was -- it's dated August 26, 2006 --</p> <p>8 A. Correct.</p> <p>9 Q. -- is that correct?</p> <p>10 And how many months before the launch of</p> <p>11 the TVT-Secur?</p> <p>12 A. This is less than one month.</p> <p>13 Q. So, less than one month before Ethicon</p> <p>14 launched the TVT-Secur, is that correct?</p> <p>15 A. Correct.</p> <p>16 Q. And -- and you've already testified that</p> <p>17 the only relevant human data that was available to</p> <p>18 demonstrate safety or efficacy of the TVT-Secur</p> <p>19 device was this First Human Use Study, is that</p> <p>20 correct?</p> <p>21 MR. SNELL: Objection and leading.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Correct.</p> <p>24 BY MR. THORNBURGH:</p>
Page 259	Page 261
<p>1 Q. What's the next exhibit you'd like to</p> <p>2 discuss, Doctor?</p> <p>3 A. P1403.</p> <p>4 MR. THORNBURGH: One moment.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And what is Exhibit --</p> <p>7 THE VIDEOGRAPHER: Your microphone.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Doctor, did you review and rely upon</p> <p>10 P1403?</p> <p>11 (Clarification requested by the</p> <p>12 reporter.)</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Did you review and rely on</p> <p>15 Exhibit P1403?</p> <p>16 A. Yes.</p> <p>17 Q. And what is Exhibit P1403?</p> <p>18 A. It's an e-mail string between David</p> <p>19 Robinson, Allison London Brown and other Ethicon</p> <p>20 employees.</p> <p>21 Q. And how, if at all, does this exhibit</p> <p>22 support your opinions?</p> <p>23 A. This is an e-mail string regarding the</p> <p>24 interim data from the first five-week data on 31</p>	<p>1 Q. Was there any other human study that</p> <p>2 demonstrate or that was available to demonstrate</p> <p>3 safety or efficacy of the TVT-Secur device at this</p> <p>4 time other than this First Human Use Study of 31</p> <p>5 patients for five weeks?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And Allison London Brown in this e-mail</p> <p>11 is writing to David Robinson who is the Medical</p> <p>12 Affairs person, is that correct?</p> <p>13 A. He is Medical Director, yes.</p> <p>14 Q. And she writes in this e-mail in the</p> <p>15 very bottom of the first page, "Anna and David,</p> <p>16 First, thanks for getting this so quickly - you've</p> <p>17 done a great job here. The data looks really</p> <p>18 promising."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Objection; leading.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Okay. And did the -- and Allison London</p> <p>24 Brown again is marketing?</p>

Bruce Alan Rosenzweig, M.D.

Page 262	Page 264
<p>1 A. She was the worldwide launch coordinator 2 for the TVT-Secur. 3 Q. Okay. And was she a medical doctor? 4 A. No. 5 Q. And she is -- is she discussing here the 6 results of the interim data? 7 A. Yes. 8 Q. And she writes here that "How best do 9 you think we need to show the data?" 10 It's the first -- she is directing this 11 question to Dave Thomas -- Dave Robinson at the 12 bottom of this page. 13 "Dave - How best do you think we need to 14 show the data? Right now it seems like it's a bit 15 passive - text and numbers on the page, but is that 16 what is needed at these meetings?" 17 And then another question, "Do you think 18 we can jazz it up a bit?" 19 Did I read that correctly? 20 MR. SNELL: Objection; leading. 21 BY THE WITNESS: 22 A. Yes. 23 BY MR. THORNBURGH: 24 Q. First of all, is it ever okay or</p>	<p>1 A. Correct. 2 BY MR. THORNBURGH: 3 Q. And do you understand what a -- what 4 does a positive cough test mean? What is that? 5 Explain to the ladies and gentlemen of the jury 6 what that test is and what the significance of that 7 test is, if any. 8 A. A cough stress test is performed with a 9 patient, most reliably in a standing position with 10 at least 200, 250 cc's of fluid in their bladder. 11 When they cough, if leakage is noted, that means 12 that there is a positive cough stress test. That 13 is a sign of stress urinary incontinence. 14 Q. And eight out of 31 had positive cough 15 tests? 16 A. Correct. 17 Q. And what does that mean, that eight out 18 of 31 had positive cough tests? 19 A. That 26% of women leaked when they were 20 asked to cough. 21 Q. If there were four women in the room who 22 underwent this procedure, how many of those women 23 would have leaked? 24 MR. SNELL: Objection.</p>
Page 263	Page 265
<p>1 appropriate for a medical device company to jazz up 2 safety or efficacy information? 3 MR. SNELL: Object. 4 BY THE WITNESS: 5 A. No. 6 BY MR. THORNBURGH: 7 Q. Why not? 8 A. Because a company should represent the 9 accurate safety and efficacy data. 10 Q. Okay. And David Robinson responds back 11 to Allison. You've already testified about this, 12 but I want to talk about it a little bit in greater 13 detail. "I am not sure I agree the data looks 14 good." 15 Is that correct? 16 A. Correct. 17 MR. SNELL: Leading. Object. 18 BY MR. THORNBURGH: 19 Q. "You are talking about a 10% failure 20 rate in the primary endpoint and eight out of 31 21 positive cough tests in our secondary endpoints." 22 Did I read that correctly? 23 MR. SNELL: Object; leading. 24 BY THE WITNESS:</p>	<p>1 BY THE WITNESS: 2 A. One of them. 3 BY MR. THORNBURGH: 4 Q. If there were 100 patients at 100 -- at 5 31 days of the five-week period and they coughed, 6 how many of them would have leaked? 7 A. 26. 8 Q. Is that a high number in your opinion, 9 Doctor? 10 A. Yes. 11 Q. At five weeks? 12 A. Yes. 13 Q. Is a 26% failure rate at five weeks good 14 or bad for patients? 15 MR. SNELL: Objection. 16 BY THE WITNESS: 17 A. That is not a positive result. 18 BY MR. THORNBURGH: 19 Q. Do you have an opinion whether or not a 20 26% failure rate was a good or bad result in this 21 study? 22 MR. SNELL: Objection. 23 BY THE WITNESS: 24 A. It was a bad result.</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 266</p> <p>1 BY MR. THORNBURGH:</p> <p>2 Q. Do you agree with David Robinson that</p> <p>3 the results of the TVT-Secur five-week study in 31</p> <p>4 patients did not look good?</p> <p>5 MR. SNELL: Object; misstates.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I agree with that statement.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Are those your words?</p> <p>10 A. Those are Dr. Robinson's words.</p> <p>11 Q. Do you agree with Dr. Robinson?</p> <p>12 A. That the data does not look good, yes.</p> <p>13 Q. Now --</p> <p>14 MR. SNELL: Move to strike.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Dr. Robinson goes on and says,</p> <p>17 "I believe these numbers will improve as the other</p> <p>18 half of the patients get done. But these first 31</p> <p>19 include everyone's learning curve."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes.</p> <p>22 Q. What's a learning curve?</p> <p>23 A. It is the amount of time that it takes</p> <p>24 for someone to become proficient at a surgical</p>	<p style="text-align: right;">Page 268</p> <p>1 BY MR. THORNBURGH:</p> <p>2 Q. Does that statement have any</p> <p>3 significance to your opinions?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And what is that?</p> <p>9 MR. SNELL: Same.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That -- well, first the learning curve,</p> <p>12 again, is the amount of time it takes a physician</p> <p>13 to feel -- to be able to reliably perform a</p> <p>14 procedure to get the best possible results.</p> <p>15 It was initially anticipated that the</p> <p>16 learning curve would be much shorter than it</p> <p>17 actually turned out to be. The learning curve was</p> <p>18 initially anticipated to be maybe five to ten</p> <p>19 cases, but was found by the opinions and internal</p> <p>20 documents from Key Opinion Leaders to be over 50</p> <p>21 and closer to 100.</p> <p>22 Q. Do you have an opinion whether or not a</p> <p>23 learning curve of 50 to 100 is a reasonable</p> <p>24 learning curve for a medical device product?</p>
<p style="text-align: right;">Page 267</p> <p>1 technique.</p> <p>2 Q. What is Dr. Robinson --</p> <p>3 THE WITNESS: Can we take a break?</p> <p>4 MR. THORNBURGH: Yes.</p> <p>5 THE VIDEOGRAPHER: The time is 3:30 p.m. and</p> <p>6 we're going off the video record.</p> <p>7 (WHEREUPON, a recess was had</p> <p>8 from 3:30 to 3:45 p.m.)</p> <p>9 THE VIDEOGRAPHER: The time is 3:45 p.m. and</p> <p>10 we're back on the video record.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Doctor, before we went off the record we</p> <p>13 were talking about Exhibit P1403, right?</p> <p>14 A. Yes.</p> <p>15 Q. And in the first part of David -- in the</p> <p>16 second sentence of David Robinson's response to</p> <p>17 Allison London Brown on August 26, 2006, he</p> <p>18 writes, "I believe these numbers will improve as</p> <p>19 the other half of the patients get done but these</p> <p>20 first 31 include everyone's learning curve."</p> <p>21 Did I read that correctly?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 269</p> <p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. It is an unreasonable learning curve.</p> <p>4 In fact, there were doctors that stated that even</p> <p>5 with training and re-training, they could still not</p> <p>6 get the same -- the results that they were striving</p> <p>7 for.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And how is the fact that there was a 50</p> <p>10 to 100 patient learning curve significant, if at</p> <p>11 all, to your opinions in this case?</p> <p>12 A. It is significant for my opinions that</p> <p>13 the Instructions for Use is defective.</p> <p>14 Q. And what about the product?</p> <p>15 A. It is also my opinion that it shows that</p> <p>16 there are characteristics of the device that make</p> <p>17 it unreasonably unsafe. Therefore, defective.</p> <p>18 Q. And, now, Dr. Robinson is saying that --</p> <p>19 he writes here that the results should get better</p> <p>20 after the physicians who are part of the research</p> <p>21 had gotten past their learning curve in the second</p> <p>22 half of the study. Is that correct?</p> <p>23 MR. SNELL: Object; leading.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 270	Page 272
<p>1 A. That's what Dr. Robinson is saying.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Since I got an objection.</p> <p>4 What is your understanding of what</p> <p>5 Dr. Robinson is suggesting with respect to the</p> <p>6 learning curve and the additional patients that</p> <p>7 would be added to the study?</p> <p>8 A. He is stating that he believes that the</p> <p>9 numbers will get better in the second half of the</p> <p>10 study. The study was to look at 60 women.</p> <p>11 Ultimately 72 women were in the final analysis of</p> <p>12 the First Human Use data, and he was anticipating</p> <p>13 that the success rates would go up and the</p> <p>14 complication rate would go down.</p> <p>15 Q. Now, was Dr. Robinson correct that after</p> <p>16 the learning curve had been achieved, that the</p> <p>17 results would get better?</p> <p>18 A. No, he was not.</p> <p>19 Q. And how do you know that? What's the</p> <p>20 basis for your opinion?</p> <p>21 A. The final data from the First Human Use</p> <p>22 Study.</p> <p>23 Q. Now, do medical device companies have</p> <p>24 choices?</p>	<p>1 sitting in New Jersey making a decision about what</p> <p>2 to do with this information, instead of</p> <p>3 Dr. Robinson, it was you, Dr. Rosenzweig, faced</p> <p>4 with the same facts and the same data, what would</p> <p>5 Dr. Rosenzweig have decided to do? What choice</p> <p>6 would you have made?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I would not have launched the TVT-Secur</p> <p>10 on September 20, 2006.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. And did you read the trial testimony of</p> <p>13 Dr. Sepulveda?</p> <p>14 A. Yes.</p> <p>15 Q. And what did Dr. Sepulveda testify to</p> <p>16 with respect to the same question I asked him, if</p> <p>17 it were Dr. Sepulveda with this information in</p> <p>18 August of 2006, what would he have done, what did</p> <p>19 he testify to?</p> <p>20 A. If --</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. If I recall correctly, he said he would</p> <p>24 delay the launch too.</p>
Page 271	Page 273
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Do the employees that work for medical</p> <p>6 device companies have choices?</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Did David Robinson have a choice in</p> <p>12 August -- on August 26, 2006 with respect to the</p> <p>13 data he had available to him prior to launch?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What choices did he have?</p> <p>19 A. He could say that this data does not</p> <p>20 look good and we should delay the launch or even</p> <p>21 not continue the product line because the data</p> <p>22 was -- showed a high failure rate and a high</p> <p>23 complication rate.</p> <p>24 Q. Now, if instead of David Robinson</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. So, do you agree with Dr. Sepulveda on</p> <p>3 that issue?</p> <p>4 A. Yes.</p> <p>5 Q. Do you agree -- and what decision did</p> <p>6 Dr. David Robinson choose?</p> <p>7 A. To continue with the launch of the</p> <p>8 TVT-Secur on September 20, 2006.</p> <p>9 Q. Was that an appropriate choice?</p> <p>10 A. No.</p> <p>11 Q. Did -- do you have an opinion whether or</p> <p>12 not Dr. Sepulveda's choice to continue with the</p> <p>13 launch of the product in light of the data he had</p> <p>14 available to him before launch --</p> <p>15 A. Dr. Robinson.</p> <p>16 Q. Sorry. Strike that.</p> <p>17 Do you have an opinion whether or not</p> <p>18 Dr. Robinson's choice to continue to launch --</p> <p>19 continue with the launch of the TVT-Secur product</p> <p>20 in light of this data was appropriate?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yes, I have an opinion.</p> <p>24 BY MR. THORNBURGH:</p>

Bruce Alan Rosenzweig, M.D.

Page 274	Page 276
<p>1 Q. What is that opinion?</p> <p>2 MR. SNELL: Same.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It was not appropriate.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And why wasn't it appropriate?</p> <p>7 A. Because the device was shown to have</p> <p>8 characteristics that made it unreasonably unsafe</p> <p>9 and unreasonably ineffective.</p> <p>10 Q. And did this decision -- do you have an</p> <p>11 opinion whether or not the decision to launch this</p> <p>12 product impacted the safety of patients?</p> <p>13 A. Yes.</p> <p>14 Q. And what is that opinion?</p> <p>15 A. That it negatively impacted the safety</p> <p>16 of women.</p> <p>17 Q. In what way?</p> <p>18 A. It had an unreasonably high failure rate</p> <p>19 and an unreasonably high complication rate.</p> <p>20 Q. What's the next document you want to</p> <p>21 discuss with the jury?</p> <p>22 A. It is an e-mail from September 25, 2006.</p> <p>23 Q. Well, hold on one second. Before we do</p> <p>24 that really quick.</p>	<p>1 A. The data did not get better. In fact,</p> <p>2 it got worse.</p> <p>3 Q. And what --</p> <p>4 A. The failure data.</p> <p>5 Q. And what was the failure rate?</p> <p>6 A. Above 30%, if I recall.</p> <p>7 Q. And is it fair to say approximately 30%</p> <p>8 of the patients who were treated with the TVT-Secur</p> <p>9 in the First Human Use Study failed the procedure</p> <p>10 to treat their stress urinary incontinence?</p> <p>11 A. Correct.</p> <p>12 MR. SNELL: Object and leading.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And what was -- what did Dr. Robinson</p> <p>15 testify to with respect to the complication rate</p> <p>16 seen by him in the final interim data of the First</p> <p>17 Human Use Study?</p> <p>18 A. That the complication data did not go</p> <p>19 down either.</p> <p>20 Q. And do you recall what the complication</p> <p>21 rate was, approximately?</p> <p>22 A. Approximately 60%.</p> <p>23 Q. Did the First Human Use final interim</p> <p>24 analysis of 31 patients at five weeks demonstrate</p>
Page 275	Page 277
<p>1 Did you read and rely on the testimony</p> <p>2 of Dr. Robinson?</p> <p>3 A. Yes.</p> <p>4 Q. And did Dr. Robinson -- what did</p> <p>5 Dr. Robinson testify with respect to the final</p> <p>6 results from the -- that short-term, five-week, 31</p> <p>7 patient interim data that he had available to him?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Prior to launch.</p> <p>11 MR. SNELL: Sorry. Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. The final 12-month analysis after the</p> <p>14 study was completed?</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Yeah, let me ask a better question.</p> <p>17 Did you read and rely on Dr. Robinson's</p> <p>18 testimony concerning the final results of the</p> <p>19 interim First Human Use data?</p> <p>20 A. Yes.</p> <p>21 Q. And what did Dr. Robinson testify to</p> <p>22 with respect to the failure rate, if any, of the</p> <p>23 TVT-Secur device as found in the final interim</p> <p>24 data?</p>	<p>1 safety or efficacy of the TVT-Secur product?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, it did not.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. What's the next document you have with</p> <p>7 you?</p> <p>8 (Reporter note: Exhibit P1452.)</p> <p>9 BY THE WITNESS:</p> <p>10 A. It is an e-mail from -- between David</p> <p>11 Robinson and Harel Gadot. It is regarding an</p> <p>12 e-mail from an Israeli physician Dr. Flam regarding</p> <p>13 defects associated with the TVT-Secur.</p> <p>14 Q. And what is the date of this e-mail?</p> <p>15 A. September 25, 2006.</p> <p>16 Q. In terms of the date that the TVT-Secur</p> <p>17 was launched, how close in time was this e-mail</p> <p>18 sent?</p> <p>19 A. Five days after launch.</p> <p>20 Q. Okay. And did you review and rely on</p> <p>21 this exhibit in forming your opinions in this case?</p> <p>22 A. Yes.</p> <p>23 Q. And what about this exhibit did you rely</p> <p>24 on in forming your opinions in this case?</p>

70 (Pages 274 to 277)

Bruce Alan Rosenzweig, M.D.

Page 278	Page 280
<p>1 A. I relied on the fact that a physician 2 who was using this device at the time who was a 3 skilled pelvic surgeon communicated with Ethicon 4 that the device was defective. 5 Q. Is it fair to say that -- strike that. 6 If we can, go ahead and just pull up 7 this exhibit on the screen and go to the full 8 e-mail from Dr. Suchard or Mr. Suchard. Very 9 bottom part. 10 And what is occurring in this 11 conversation with Dr. Suchard to Dr. Flam Folke? 12 MR. SNELL: Objection. 13 BY MR. THORNBURGH: 14 Q. What part of this -- what part of this 15 e-mail conversation is relevant to your opinions? 16 A. Well, first, Dr. Flam is being invited 17 to some professional education events for TVT-Secur 18 and Prolift from the Gynecare team leader from 19 Johnson & Johnson medical in Israel. 20 Q. Did -- I'm sorry. Go ahead. Go ahead. 21 A. And then Dr. Flam responds back that he 22 has concerns regarding the TVT-Secur. He feels 23 that the product needs to be adjusted before he's 24 willing to demonstrate it. He describes that there</p>	<p>1 off to Dr. Robinson and said, "Please do not 2 distribute." 3 BY MR. THORNBURGH: 4 Q. And what is the significance of that 5 response from Dr. Gadot saying, "FYI - please do 6 not distribute"? 7 A. Well, if this information about the 8 defects associated with the TVT-Secur device are 9 not distributed to -- to others, then it would be 10 difficult or impossible for doctors to know about 11 the defects, the characteristics of the device that 12 make it defective and that make it unreasonably 13 unsafe or unreasonably ineffective and therefore 14 cannot pass that information on to their patients 15 to have an adequate, informed discussion about the 16 risks associated with the TVT-Secur device. 17 Q. Do you have an opinion about whether or 18 not Ethicon appropriately responded to the concerns 19 being raised by Dr. Flam Folke? 20 MR. SNELL: Object. 21 BY THE WITNESS: 22 A. I do have an opinion. 23 BY MR. THORNBURGH: 24 Q. What's that opinion?</p>
Page 279	Page 281
<p>1 are defects that have to be attended to. 2 Q. And did -- do you agree -- 3 MR. SNELL: I'm sorry. Move to strike. 4 BY MR. THORNBURGH: 5 Q. Do you agree -- based on your review of 6 the -- strike that. 7 Do you agree with Dr. Flam Folke or 8 Folke? 9 A. Yes. 10 Q. And what part of Dr. Flam Folke's e-mail 11 do you agree with? 12 MR. SNELL: Object. 13 BY THE WITNESS: 14 A. That there are defects associated with 15 the TVT-Secur. 16 BY MR. THORNBURGH: 17 Q. And how did Ethicon or Ethicon's 18 employees respond to this comment by Dr. Folke that 19 the TVT-Secur had some defects that needed to be 20 attended to? 21 A. When it went up to -- 22 MR. SNELL: Object. 23 BY THE WITNESS: 24 A. -- a member or Dr. Gadot forward this</p>	<p>1 A. They did not. 2 Q. And how so? 3 A. They did not distribute this information 4 from a surgeon who noted that there were defects 5 associated with the TVT-Secur. 6 Q. Do you have an opinion whether or not 7 Ethicon had enough information at this point in 8 time to take proper action and, as Dr. Folke 9 writes, address or attend to some of the defects? 10 MR. SNELL: Object. 11 BY THE WITNESS: 12 A. Yes, they did have enough information. 13 BY MR. THORNBURGH: 14 Q. What information did they have? 15 A. The data from the First Human Use Study. 16 Q. And did Ethicon attempt in any way to 17 correct or address the physical characteristics of 18 the TVT-Secur device from the date that they 19 launched it until they finally stopped selling the 20 product in 2012? 21 MR. SNELL: Object. 22 BY THE WITNESS: 23 A. No, they did not. 24 BY MR. THORNBURGH:</p>

Bruce Alan Rosenzweig, M.D.

Page 282	Page 284
<p>1 Q. And do you have an opinion about whether</p> <p>2 or not that was appropriate?</p> <p>3 A. I do have an opinion.</p> <p>4 Q. And what's that opinion?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. It is inappropriate.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And what should the company do?</p> <p>10 MR. SNELL: Same objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Stop selling the device.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. How many years did it take after</p> <p>15 Dr. Folke's or Folke's e-mail with the comment that</p> <p>16 there were some defects that needed to be attended</p> <p>17 to before Ethicon stopped selling the device?</p> <p>18 A. Six years.</p> <p>19 Q. And all this time, the six-year period,</p> <p>20 did doctors continue to implant the TVT-Secur</p> <p>21 product into patients?</p> <p>22 A. Yes.</p> <p>23 Q. Did Ethicon's failure to properly</p> <p>24 respond to the data from their First Human Use</p>	<p>1 BY THE WITNESS:</p> <p>2 A. -- to treat their stress urinary</p> <p>3 incontinence and the complications associated with</p> <p>4 the device, including erosion, pain, pain with</p> <p>5 intercourse, obstructed voiding, irritative voiding</p> <p>6 symptoms that I've described earlier in prior</p> <p>7 testimony.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Could Ethicon have taken action,</p> <p>10 different action?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Should Ethicon have responded and</p> <p>16 attended to the defects?</p> <p>17 A. Yes.</p> <p>18 MR. SNELL: Object.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Is there anything else significant from</p> <p>21 that exhibit?</p> <p>22 A. No.</p> <p>23 Q. What's the next exhibit that you have</p> <p>24 and wish to discuss with the jury?</p>
Page 283	Page 285
<p>1 Study and to the concerns of Dr. Folke put patients</p> <p>2 at risk?</p> <p>3 MR. SNELL: Object and leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Do you have an opinion whether or not</p> <p>8 Ethicon's failure to respond by attending to the</p> <p>9 defects put patients at risk of harm?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes, I have an opinion.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. What's that opinion?</p> <p>15 MR. SNELL: Same.</p> <p>16 BY THE WITNESS:</p> <p>17 A. That my opinion is that that -- not</p> <p>18 attending to the defects associated with the device</p> <p>19 put patients at harm.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What types of harm are patients put at</p> <p>22 risk of suffering from?</p> <p>23 A. Failure of the device --</p> <p>24 MR. SNELL: Object.</p>	<p>1 A. It is an e-mail string between Ethicon</p> <p>2 employees Carolyn Brennan and Mark Yale discussing</p> <p>3 the learning curve and complications that are being</p> <p>4 reported to Ethicon.</p> <p>5 Q. Okay. And can you identify the exhibit</p> <p>6 number for the ladies and gentlemen of the jury?</p> <p>7 A. P0274.</p> <p>8 Q. Okay. And what's the date of this</p> <p>9 e-mail string?</p> <p>10 A. November 3, 2006.</p> <p>11 Q. And did you review and rely on this</p> <p>12 exhibit?</p> <p>13 A. Yes.</p> <p>14 Q. And what, if anything, is significant to</p> <p>15 your opinions in Exhibit 274?</p> <p>16 A. Based on the complications and</p> <p>17 difficulties that surgeons are having, one of the</p> <p>18 Ethicon employees who's Project Manager, Worldwide</p> <p>19 Customer Quality, Cary Brennan, is raising concerns</p> <p>20 about whether it is the surgeon's learning curve,</p> <p>21 it is the technique of insertion or is it an inmate</p> <p>22 problem with the device, a defect with the device</p> <p>23 that is leading to the difficulties that the</p> <p>24 doctors are having.</p>

72 (Pages 282 to 285)

Bruce Alan Rosenzweig, M.D.

Page 286	Page 288
<p>1 Q. And do you -- what was the subject that</p> <p>2 Ethicon employees were discussing in this e-mail?</p> <p>3 A. Difficulties with insertion of the</p> <p>4 device.</p> <p>5 Q. Okay. And the -- I think the question</p> <p>6 that you discussed was, if you look at Exhibit 274,</p> <p>7 it says, "Our concern is whether this is the</p> <p>8 surgeon's learning curve, technique issue or a</p> <p>9 problem with the device."</p> <p>10 Did I read that correctly?</p> <p>11 MR. SNELL: Objection; leading too.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Correct.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And how many months after the TVT-Secur</p> <p>16 product had already been launched into the</p> <p>17 worldwide market to be implanted permanently in</p> <p>18 women did people or employees at Ethicon discuss</p> <p>19 these concerns?</p> <p>20 A. Approximately six weeks after launch.</p> <p>21 Q. Do you have an opinion whether or not</p> <p>22 these concerns should have been discussed and</p> <p>23 determined and attended to before the product had</p> <p>24 ever been launched?</p>	<p>1 then the device not continued or removed from the</p> <p>2 market.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What's -- is there anything else</p> <p>5 significant about that last exhibit?</p> <p>6 A. No.</p> <p>7 Q. What's the next exhibit that you'd like</p> <p>8 to discuss?</p> <p>9 A. Again, it is Exhibit P1096. It is an</p> <p>10 e-mail string between key Ethicon employees, Dr. --</p> <p>11 excuse me -- Harel Gadot of marketing and Ralf</p> <p>12 Felix Gotter, who is the country director of</p> <p>13 Ethicon in Germany.</p> <p>14 Q. And what -- what was the subject of the</p> <p>15 discussion being held between these Ethicon</p> <p>16 employees on November 30 of 2006?</p> <p>17 A. Yes. More procedures, more problems.</p> <p>18 Q. And how is this document relevant, if at</p> <p>19 all, to your opinions in this case?</p> <p>20 A. This is documenting the defects</p> <p>21 associated with the device, which are leading to</p> <p>22 harm in women, which are now being reported to</p> <p>23 Ethicon.</p> <p>24 The more procedures that are being done,</p>
Page 287	Page 289
<p>1 A. Yes, I have an opinion.</p> <p>2 MR. SNELL: Objection; leading.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What's that opinion?</p> <p>5 MR. SNELL: Same.</p> <p>6 BY THE WITNESS:</p> <p>7 A. That these issues should have been</p> <p>8 attended to prior to launch.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And what could Ethicon have done</p> <p>11 differently to attend to these issues to determine</p> <p>12 whether or not what is being reported here were a</p> <p>13 result of the learning curve, technique issue or</p> <p>14 problem with the device?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Studying the device in a prospective</p> <p>18 randomized controlled fashion or in other human use</p> <p>19 studies would have demonstrated the characteristics</p> <p>20 of the device that make it either difficult to</p> <p>21 insert or unreasonably unsafe for patients or</p> <p>22 unreasonably ineffective for patients.</p> <p>23 Those could have been identified and</p> <p>24 changed or if those could not have been changed,</p>	<p>1 the more complications that are occurring,</p> <p>2 demonstrating the characteristics of the device</p> <p>3 that are unreasonably unsafe.</p> <p>4 Q. And was it appropriate -- strike that.</p> <p>5 Is there anything else relevant to this</p> <p>6 exhibit or significant to your opinions with</p> <p>7 respect to this exhibit?</p> <p>8 A. No.</p> <p>9 Q. What's the next document in your binder?</p> <p>10 A. It is an e-mail string between David</p> <p>11 Robinson, Medical Director, and other key Ethicon</p> <p>12 employees regarding concerns about the</p> <p>13 effectiveness of the device as seen by doctors who</p> <p>14 are teaching the procedure to other doctors, which</p> <p>15 are called preceptors, and also from the interim</p> <p>16 analysis of the First Human Use Study,</p> <p>17 demonstrating the characteristics of the device</p> <p>18 that make it unreasonably ineffective and leading</p> <p>19 to the harm of either not treating the stress</p> <p>20 urinary incontinence or recurrence of stress</p> <p>21 urinary incontinence.</p> <p>22 Q. How many months after Ethicon had</p> <p>23 already launched this product into the worldwide</p> <p>24 market did Ethicon --</p>

73 (Pages 286 to 289)

Bruce Alan Rosenzweig, M.D.

Page 290	Page 292
<p>1 MR. SNELL: I'm sorry. I have to actually</p> <p>2 object to as non-responsive and well beyond the</p> <p>3 question for the last answer.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Let me ask you this question, Doctor.</p> <p>6 What is the significance, if any, of this</p> <p>7 Exhibit P127 to your opinions?</p> <p>8 A. This e-mail string demonstrates that</p> <p>9 Ethicon had information regarding the poor efficacy</p> <p>10 in treating stress urinary incontinence or</p> <p>11 effectiveness in treating stress urinary</p> <p>12 incontinence of the TVT-Secur device within two</p> <p>13 months of launch.</p> <p>14 Q. Okay. And if we look at -- what</p> <p>15 paragraph or part of Exhibit P127 supports your</p> <p>16 opinions?</p> <p>17 A. The e-mail states, "It is apparent that</p> <p>18 there is some level of concern re efficacy seen by</p> <p>19 the preceptors," again, which are doctors that are</p> <p>20 training other doctors to do the technique, "as</p> <p>21 well as within the interim analysis of the First</p> <p>22 Human Use Trials."</p> <p>23 Q. Okay. And where were these physicians</p> <p>24 located who were raising concerns about the</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Who is -- who is -- in the first -- who</p> <p>3 is being addressed in this document?</p> <p>4 A. Dharini Amin who is an Ethicon employee</p> <p>5 of Johnson & Johnson.</p> <p>6 Q. Okay. And David Robinson writes,</p> <p>7 "Dharini, on another note, I think Marketing (and</p> <p>8 you in particular) need to think about some issues</p> <p>9 that are going to come forth with Secur."</p> <p>10 Did I read that correctly?</p> <p>11 MR. SNELL: Object; leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What, if any, significance does that</p> <p>16 sentence have with respect to your opinions?</p> <p>17 A. That sentence demonstrates that Ethicon</p> <p>18 had knowledge as early as November 14, 2006 about</p> <p>19 concerns with the TVT-Secur regarding its</p> <p>20 effectiveness and characteristics of the device</p> <p>21 that made it unreasonably unsafe.</p> <p>22 MR. SNELL: Object. Move to strike. State of</p> <p>23 mind.</p> <p>24 BY MR. THORNBURGH:</p>
Page 291	Page 293
<p>1 TVT-Secur device and its efficacy?</p> <p>2 A. Both U.S. preceptors and European,</p> <p>3 Middle East and Africa preceptors.</p> <p>4 Q. Okay. If Ethicon were to represent</p> <p>5 that -- assume with me that at trial Ethicon, their</p> <p>6 experts or through argument, represents to the</p> <p>7 ladies and gentlemen of the jury that the problems</p> <p>8 with the TVT-Secur device with respect to its</p> <p>9 efficacy were isolated to Australia or Germany,</p> <p>10 would that be an accurate statement?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Why not?</p> <p>16 A. What we're seeing here is concern from</p> <p>17 preceptors, both in the United States and in</p> <p>18 Europe, Middle East and Africa, about concerns</p> <p>19 regarding the effectiveness in treating stress</p> <p>20 urinary incontinence of the product.</p> <p>21 Q. And, in fact, if we look at this first</p> <p>22 paragraph, it's Dr. Robinson writing to Dharini, is</p> <p>23 that correct?</p> <p>24 MR. SNELL: Object; leading.</p>	<p>1 Q. And he -- Dr. Robinson goes on and says</p> <p>2 or writes, "After listening to the U.S. preceptors</p> <p>3 and also going to the EMEA," which we've already</p> <p>4 established was the European -- Europe, Middle East</p> <p>5 and Africa, "preceptor/early use meeting this</p> <p>6 weekend in Paris, it is apparent that there is some</p> <p>7 level of concern regarding efficacy seen by</p> <p>8 preceptors as well as within the interim analysis</p> <p>9 of the First Human Use Trial."</p> <p>10 Did I read that correctly?</p> <p>11 MR. SNELL: Object and leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What is significant, if any, with</p> <p>16 respect to that statement by Dr. Robinson?</p> <p>17 MR. SNELL: Same objection and leading.</p> <p>18 BY THE WITNESS:</p> <p>19 A. That statement describes concern about</p> <p>20 the effectiveness of the TVT-Secur both as noted by</p> <p>21 doctors that are using it and also in the first</p> <p>22 study, Human Use Study conducted by Ethicon.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Dr. Rosenzweig, is Dr. Robinson</p>

Bruce Alan Rosenzweig, M.D.

Page 294	Page 296
<p>1 reporting that after the device was launched on to</p> <p>2 the market doctors throughout the world were having</p> <p>3 the same problems that Ethicon, particularly</p> <p>4 Dr. David Robinson, was made aware of prior to</p> <p>5 launching the product when he looked at the First</p> <p>6 Human Use data?</p> <p>7 MR. SNELL: Objection and leading.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. What, if anything, is significant about</p> <p>12 Dr. Robinson's statements here concerning the</p> <p>13 problems that are being reported by Ethicon's</p> <p>14 preceptors around the world in relationship to what</p> <p>15 was seen before the product was launched by</p> <p>16 Dr. Robinson in the First Human Use interim data?</p> <p>17 MR. SNELL: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Dr. Robinson is reporting that doctors</p> <p>20 who are trying to implant the device are</p> <p>21 experiencing the same degree of inability of the</p> <p>22 product to treat the stress urinary incontinence as</p> <p>23 was known from the First Human Use Study prior to</p> <p>24 launch of the product.</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes, by not launching the product or</p> <p>3 removing the product from the market.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. I mean, we're not just talking about</p> <p>6 doctors having problems, are we?</p> <p>7 MR. SNELL: Objection; leading, argumentative.</p> <p>8 Sorry. Go ahead.</p> <p>9 BY THE WITNESS:</p> <p>10 A. No.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. What are we talking about here?</p> <p>13 A. The safety --</p> <p>14 MR. SNELL: Same.</p> <p>15 BY THE WITNESS:</p> <p>16 A. -- of patients.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And, so, when Dr. Robinson is talking</p> <p>19 about these preceptors who were reporting their</p> <p>20 concerns, is he -- is it your understanding that</p> <p>21 he's -- that these concerns are with respect to</p> <p>22 actual people?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>
Page 295	Page 297
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And you testified earlier about choices,</p> <p>3 about how Ethicon and David Robinson in particular</p> <p>4 had a choice when he looked at the first interim</p> <p>5 use data. Do you recall that?</p> <p>6 A. Yes.</p> <p>7 MR. SNELL: Objection; leading.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And do you recall the testimony about</p> <p>10 why those choices that he had were important?</p> <p>11 A. Yes.</p> <p>12 Q. And what was your statement?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. That it is important to look at the data</p> <p>16 to determine whether or not to go ahead with the</p> <p>17 launch of the product and based on the data, the</p> <p>18 product should not have been launched.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And the problems that were being</p> <p>21 expressed by Ethicon's preceptors both in the</p> <p>22 United States and in other parts of the world,</p> <p>23 could those problems have been avoided?</p> <p>24 MR. SNELL: Object.</p>	<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And, so, when you testified earlier that</p> <p>4 Ethicon and David Robinson in particular had a</p> <p>5 choice and that they could have chosen to delay the</p> <p>6 launch to fix the problems or not to launch the</p> <p>7 product at all and that by making the choice to put</p> <p>8 the product on the market despite the First Human</p> <p>9 Use data and how that could impact patient safety,</p> <p>10 is that what we're actually seeing in the real</p> <p>11 world?</p> <p>12 MR. SNELL: Object and leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Doctor, I got a leading objection.</p> <p>17 How does this document, Exhibit P127,</p> <p>18 support the prior testimony from you that it was</p> <p>19 inappropriate for Ethicon to release or launch the</p> <p>20 TVT-Secur data in light of the First Human Use</p> <p>21 Trial?</p> <p>22 MR. SNELL: Same objection. No leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. This demonstrates that doctors were</p>

75 (Pages 294 to 297)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 298</p> <p>1 having problems with the device and it was putting</p> <p>2 patients at harm.</p> <p>3 THE VIDEOGRAPHER: Counsel, can I end?</p> <p>4 MR. THORNBURGH: We have to take a break for a</p> <p>5 tape change.</p> <p>6 THE VIDEOGRAPHER: The time is 4:21 p.m. This</p> <p>7 is the end of Tape 3 and we're going off the video</p> <p>8 record.</p> <p>9 (WHEREUPON, a recess was had</p> <p>10 from 4:21 to 4:31 p.m.)</p> <p>11 THE VIDEOGRAPHER: The time is 4:31 p.m. This</p> <p>12 is the beginning of Tape 4 and we are back on the</p> <p>13 video record.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Dr. Rosenzweig, before we went off the</p> <p>16 record we were discussing Exhibit P127, and we're</p> <p>17 almost through with this exhibit, but I want to</p> <p>18 take you back in time just a little bit.</p> <p>19 This is November of 2006 when this</p> <p>20 discussion is occurring and, again, you testified</p> <p>21 that was just a couple months after Ethicon had</p> <p>22 launched the product?</p> <p>23 A. Correct.</p> <p>24 Q. Now, you also testified earlier that</p>	<p style="text-align: right;">Page 300</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Would that type of information have been</p> <p>5 important to you?</p> <p>6 A. Yes.</p> <p>7 Q. In what way?</p> <p>8 A. It would have been important to know</p> <p>9 whether a device is safe and effective to be used</p> <p>10 in humans in order to decide what is the most</p> <p>11 appropriate therapy to use in an individual</p> <p>12 patient.</p> <p>13 Q. Is that the type of information that</p> <p>14 physicians use in the method that we discussed</p> <p>15 earlier of the risk/benefit assessment when</p> <p>16 deciding which surgical or treatment options should</p> <p>17 be made available to their patients?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Is there anything else relevant that you</p> <p>23 want to speak with the jury about concerning</p> <p>24 Exhibit 127?</p>
<p style="text-align: right;">Page 299</p> <p>1 shortly after the launch of the TVT-Secur, either</p> <p>2 at the end of 2006 or beginning of 2007, you were</p> <p>3 introduced to the TVT-Secur through Ethicon's sales</p> <p>4 representative?</p> <p>5 A. Correct.</p> <p>6 MR. SNELL: Object.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And did Ethicon sales representative</p> <p>9 ever inform you that Ethicon's internal first human</p> <p>10 interim data showed 60% complication rate or 30%</p> <p>11 failure rate?</p> <p>12 A. No.</p> <p>13 Q. Did Ethicon ever through its sales</p> <p>14 representative when she met with you at the end of</p> <p>15 2006 or 2007 ever inform you that physicians around</p> <p>16 the world were experiencing problems with the</p> <p>17 efficacy of the TVT-Secur device?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Is that the type of information that is</p> <p>23 important to implanting physicians?</p> <p>24 MR. SNELL: Same.</p>	<p style="text-align: right;">Page 301</p> <p>1 A. No.</p> <p>2 Q. What's the next document that you want</p> <p>3 to discuss?</p> <p>4 A. It is an e-mail string between Medical</p> <p>5 Directors Dr. Robinson, Dr. Arnaud and Dan Smith.</p> <p>6 Q. And what is the exhibit number, if you</p> <p>7 can identify that for the ladies and gentlemen of</p> <p>8 the jury?</p> <p>9 A. P0619.</p> <p>10 Q. And can you describe to the ladies and</p> <p>11 gentlemen of the jury what P619 is?</p> <p>12 A. It is an e-mail string from Medical</p> <p>13 Directors and also Dan Smith, who was the lead</p> <p>14 engineer and also co-inventor of the TVT-Secur,</p> <p>15 regarding putting together what was called a</p> <p>16 cookbook to help physicians overcome their</p> <p>17 difficulties with implanting the device and in</p> <p>18 order to try to improve the success rate.</p> <p>19 What this document demonstrates is that</p> <p>20 the Instructions for Use was defective because it</p> <p>21 could not be used by a physician to effectively,</p> <p>22 accurately and reliably insert the TVT-Secur</p> <p>23 device.</p> <p>24 MR. SNELL: Object; beyond the question. Move</p>

Bruce Alan Rosenzweig, M.D.

Page 302	Page 304
<p>1 to strike.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. So, what is the significance, if</p> <p>4 anything, of Exhibit P619 to your opinions?</p> <p>5 A. It demonstrates that the IFU is</p> <p>6 defective.</p> <p>7 Q. Now, Doctor, I thought you testified</p> <p>8 that Ethicon had performed design validations to</p> <p>9 validate the information and instructions they were</p> <p>10 providing to physicians in the TVT-Secur IFU?</p> <p>11 MR. SNELL: Object; leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Is it correct or incorrect that Ethicon</p> <p>16 performed design validations to determine the</p> <p>17 validity and accuracy of the information they were</p> <p>18 providing concerning the proper implantation</p> <p>19 technique to be used when implanting patients with</p> <p>20 the TVT-Secur device?</p> <p>21 A. Yes.</p> <p>22 Q. And in this case you just testified a</p> <p>23 moment ago that this Exhibit 619 demonstrates that</p> <p>24 the IFU is defective?</p>	<p>1 December 2006. They are already having discussions</p> <p>2 about trying to put a reference guide or what's</p> <p>3 called a cookbook to help doctors place the device</p> <p>4 safely, effectively or reliably in women because</p> <p>5 the Instructions for Use was not adequate in order</p> <p>6 to accomplish that.</p> <p>7 Q. Do you have an opinion whether or not</p> <p>8 Ethicon should have or could have -- strike that.</p> <p>9 Do you have an opinion whether or not</p> <p>10 Ethicon could have -- strike that.</p> <p>11 Do you have an opinion whether or not</p> <p>12 Ethicon could have slowed down the launch of this</p> <p>13 product, taken its time in design validation to</p> <p>14 provide more accurate, clear information in its</p> <p>15 IFU?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What's that opinion?</p> <p>21 MR. SNELL: Same.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That they could have slowed the process</p> <p>24 down.</p>
Page 303	Page 305
<p>1 A. Correct.</p> <p>2 MR. SNELL: Objection; leading.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. First of all, it would be that the IFU</p> <p>5 was defective, is that correct?</p> <p>6 A. Correct.</p> <p>7 MR. SNELL: Same objection.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Because Ethicon is no longer selling the</p> <p>10 Secur device, is that correct?</p> <p>11 MR. SNELL: Same objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Correct.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Is Ethicon still selling the Secur</p> <p>16 device?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. It is not in the United States.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Okay. And how does this exhibit</p> <p>22 support, if at all, your opinion that the TVT</p> <p>23 IFU -- Secur IFU was defective?</p> <p>24 A. Well, this is an e-mail from the 19th of</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And do you have an opinion whether or</p> <p>3 not the defects that you describe with respect to</p> <p>4 the IFU -- strike that.</p> <p>5 Do you have an opinion whether or not</p> <p>6 the defects you describe with respect to the IFU</p> <p>7 were caused by the conduct of Ethicon or its</p> <p>8 employees?</p> <p>9 MR. SNELL: Objection; leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I don't understand the question.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Yeah. Sorry.</p> <p>14 Do you have an opinion one way or the</p> <p>15 other how the TVT-Secur IFU became defective?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Let me ask a better question.</p> <p>19 You just testified a moment ago that</p> <p>20 this document supports your opinion that the</p> <p>21 TVT-Secur IFU was defective?</p> <p>22 A. Correct.</p> <p>23 Q. Do you have an opinion about why it was</p> <p>24 defective or how it became defective?</p>

77 (Pages 302 to 305)

Bruce Alan Rosenzweig, M.D.

Page 306	Page 308
<p>1 MR. SNELL: Objection. Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. The TVT-Secur device is inherently</p> <p>4 defective. The TVT-Secur IFU is inherently</p> <p>5 defective.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Was there any --</p> <p>8 MR. SNELL: I'm going to move to strike as</p> <p>9 non-responsive.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. You had testified earlier about</p> <p>12 Ethicon's concern about getting the TVT-Secur on</p> <p>13 the market first before its competitors released</p> <p>14 their mini-sling. Do you recall that testimony?</p> <p>15 A. Yes.</p> <p>16 Q. Do you have an opinion whether or not</p> <p>17 their decision to move quickly to launch the</p> <p>18 TVT-Secur product had any or played any role in the</p> <p>19 information or the lack of accurate information</p> <p>20 that made its way or failed to make its way into</p> <p>21 the TVT-Secur IFU?</p> <p>22 MR. SNELL: Object; leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>	<p>1 make its way into the TVT-Secur IFU?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, it did not.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And is it appropriate -- do you have an</p> <p>7 opinion whether or not it's appropriate for a</p> <p>8 company to fail to update the Information for Use</p> <p>9 that they provide with medical devices if they</p> <p>10 determine that the Information for Use was</p> <p>11 inaccurate or unclear?</p> <p>12 MR. SNELL: Objection and leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. If the Instructions for Use are deemed</p> <p>15 to be inaccurate or unclear, then the Instructions</p> <p>16 for Use need to be changed to make it accurate and</p> <p>17 clear.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Could Ethicon have -- could Ethicon --</p> <p>20 did Ethicon have a choice in whether or not to</p> <p>21 update the TVT-Secur IFU?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>
Page 307	Page 309
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And what is that opinion?</p> <p>3 A. That that contributed to the IFU being</p> <p>4 defective.</p> <p>5 Q. All right. Now, what part of</p> <p>6 Exhibit 619 support your opinions?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. This e-mail string goes through a</p> <p>10 discussion between Medical Directors and Dan Smith</p> <p>11 regarding that the cookbook was different from the</p> <p>12 Instructions for Use; that if they decide to do a</p> <p>13 cookbook, they would need to validate a new IFU,</p> <p>14 which a cookbook cannot do.</p> <p>15 Q. Now, did Ethicon ever --</p> <p>16 MR. SNELL: I'm sorry. Object. Move to</p> <p>17 strike. Reading. Go ahead.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Did Ethicon ever update its -- the</p> <p>20 TVT-Secur IFU?</p> <p>21 A. No, they did not.</p> <p>22 Q. Did the learnings from this time period</p> <p>23 where Axel Arnaud and David Robinson were drafting</p> <p>24 a TVT-Secur cookbook, did that information ever</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Was it -- do you have an opinion whether</p> <p>3 or not it was appropriate or inappropriate for</p> <p>4 Ethicon to fail to update its IFU?</p> <p>5 MR. SNELL: Object and leading.</p> <p>6 BY THE WITNESS:</p> <p>7 A. It was inappropriate to not update the</p> <p>8 IFU.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Why is that?</p> <p>11 A. Because if the IFU is defective, it</p> <p>12 needs to be changed to make it not defective or the</p> <p>13 product needs to be removed from the market.</p> <p>14 Q. And if we turn to ETH.MESH.01000734 of</p> <p>15 Exhibit 619, there's an e-mail from Dan Smith to</p> <p>16 Axel.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And what is Dan Smith telling</p> <p>20 Axel Arnaud concerning the draft IFU that</p> <p>21 Dr. Arnaud had distributed or sent to Dan Smith and</p> <p>22 David Robinson?</p> <p>23 MR. SNELL: Object and leading.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 310	Page 312
<p>1 A. He is stating, "I have major 2 difficulties with this document. I don't know 3 where to start. I have not even looked at the U. 4 It cannot go out like this, nor do I believe this 5 is what is needed. Everything in the blue shade is 6 either wrong or needs much work to align with the 7 Instructions for Use and I'm not writing another 8 Instructions for Use. The Instructions for Use 9 contains detailed information that they must 10 follow. This document should be a cheat sheet and 11 not another IFU." 12 Q. Now, Axel Arnaud is the Medical 13 Director? 14 A. Yes. 15 Q. And Dan Smith is an engineer? 16 A. Correct. 17 Q. Based on your review of the internal 18 documents, did Dan Smith have any formal medical 19 training? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. No. 23 BY MR. THORNBURGH: 24 Q. In your opinion based on your review of</p>	<p>1 They have a hard time to achieve consistently good 2 results with the device." 3 BY MR. THORNBURGH: 4 Q. And, now, if you go down to the next 5 paragraph, there's a statement by Dr. Axel Arnaud 6 that "The answers to the surgeon's questions not 7 being in the IFU, there is a need for what made the 8 reproducibility and success of both TVT and TVT-O, 9 i.e., a 'cookbook.'" 10 He goes on to write, "The documents I 11 sent you are based on the opinion of numerous 12 European experts and pearls from U.S. surgeons." 13 What does that statement by Dr. Arnaud 14 indicate to you? 15 MR. SNELL: Objection; leading. 16 BY THE WITNESS: 17 A. That the IFU is defective because it -- 18 there are surgeons' questions that are not answered 19 by the Instructions for Use. 20 BY MR. THORNBURGH: 21 Q. And how does Dr. Dan Smith respond? 22 A. Mr. -- 23 Q. I'm sorry. Strike that. 24 How does Mr. Dan Smith, the engineer at</p>
Page 311	Page 313
<p>1 Ethicon's internal documents, was it appropriate 2 for Dan Smith to push back against the possibility 3 to update or draft a new TVT-Secur IFU? 4 MR. SNELL: Object. 5 BY THE WITNESS: 6 A. No, it was not. 7 BY MR. THORNBURGH: 8 Q. Why not? 9 A. Because if the IFU is defective, it 10 needs to be changed, if it could be changed, or the 11 product needs to be removed from the market. 12 Q. If you move to ETH.MESH number ending in 13 733, there is a response from Dr. Arnaud to 14 Dan Smith. And can you -- what, if anything, is 15 significant about this response? 16 MR. SNELL: Object; leading. 17 BY THE WITNESS: 18 A. Dr. Arnaud is writing, "I've had a hard 19 time to understand how you can state what is wrong 20 or what is right, what must be followed or not, 21 what is needed or not, when many of our customers 22 themselves do not know after their initial 23 experience" -- "our customers themselves still do 24 not know after their initial experience with Secur.</p>	<p>1 Ethicon, respond? 2 MR. SNELL: Object and leading. 3 BY THE WITNESS: 4 A. That they would have to validate that 5 with a new Instructions for Use. 6 BY MR. THORNBURGH: 7 Q. And if we show that real quick on the 8 page beginning on ETH.MESH ending in 732. The very 9 last sentence. 10 A. "If you choose to go down that path as 11 you have written, you must assemble a team and 12 follow the U.S. design control procedures to 13 validate a new Instructions for Use as we can NOT 14 have a cookbook which differs from the package 15 insert." 16 Q. Did Ethicon ever go back to the drawing 17 board and validate a new TVT-Secur IFU? 18 MR. SNELL: Object; leading. 19 BY THE WITNESS: 20 A. No. 21 BY MR. THORNBURGH: 22 Q. Do you have an opinion whether or not 23 Ethicon could have done that? 24 A. Yes, I do have an opinion.</p>

Bruce Alan Rosenzweig, M.D.

Page 314	Page 316
<p>1 Q. Do you have an opinion whether or not</p> <p>2 Ethicon should have done that?</p> <p>3 A. Yes, I have an opinion.</p> <p>4 Q. And what are those opinions?</p> <p>5 A. They could have done that and should</p> <p>6 have done that.</p> <p>7 Q. Is there anything else you'd like to</p> <p>8 discuss with respect to Exhibit 619?</p> <p>9 A. No.</p> <p>10 Q. What's the next document you'd like to</p> <p>11 discuss?</p> <p>12 A. It is an e-mail on -- from January 16,</p> <p>13 2007 from key Ethicon employees, including Harel</p> <p>14 Gadot, Axel Arnaud, discussing the French TVT-Secur</p> <p>15 data.</p> <p>16 Q. And what's the exhibit number?</p> <p>17 A. P1100.</p> <p>18 Q. And what, if anything, is significant to</p> <p>19 your opinions with respect to Exhibit 1100?</p> <p>20 A. This e-mail also confirms that doctors</p> <p>21 in France were having concerns about the efficacy</p> <p>22 of the TVT-Secur.</p> <p>23 Q. Can you direct us to the part or parts</p> <p>24 of this exhibit that you rely on for -- to support</p>	<p>1 included and/or stop for a while such publication</p> <p>2 that could compromise the future."</p> <p>3 Q. And what opinion does that statement by</p> <p>4 Dr. Buchon or Xavier Buchon support?</p> <p>5 A. That Ethicon was not sharing negative</p> <p>6 information with doctors. It is -- this e-mail is</p> <p>7 stating that they would rather stop publication</p> <p>8 that would compromise the future of the TVT-Secur.</p> <p>9 Q. And is it appropriate for medical device</p> <p>10 companies to attempt to stop medical publications</p> <p>11 concerning the safety of their products?</p> <p>12 A. No.</p> <p>13 Q. Is it appropriate for companies to</p> <p>14 attempt to manipulate data related to safety or</p> <p>15 efficacy of their permanent medical device</p> <p>16 products?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. No.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. So, if we just break this down really</p> <p>22 quick, on page -- on the first page of this</p> <p>23 exhibit, the response to Fabrice's concerns, it</p> <p>24 states, "This is for sure a big concern and I would</p>
Page 315	Page 317
<p>1 your opinion?</p> <p>2 A. Yes. "I was with Dr. Jacquetin today.</p> <p>3 He is currently collecting data on Secur. My main</p> <p>4 concern is the outcome of their data, the success</p> <p>5 rate following TVT-Secur" -- excuse me --</p> <p>6 "implementation is way below TVT-O or TVT around 80</p> <p>7 to 85%."</p> <p>8 Q. And what, if anything, is significant</p> <p>9 about that part of this e-mail?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. It is confirmed -- it confirms that</p> <p>13 doctors are having concerns about the success rate</p> <p>14 for the TVT-Secur.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And is there anything else -- are there</p> <p>17 any other portions of this exhibit that you rely on</p> <p>18 to support your opinions?</p> <p>19 A. Yes.</p> <p>20 Q. Can you direct us there?</p> <p>21 A. It is the follow-up to that.</p> <p>22 "This is for sure a big concern. I</p> <p>23 would recommend to have your support as well as</p> <p>24 Axel's, potentially review the patients to be</p>	<p>1 recommend we have your support as well as Axel,</p> <p>2 potentially review the patients to be included</p> <p>3 and/or stop for a while such publications that</p> <p>4 could compromise the future. No way to hide the</p> <p>5 truth but to make sure it has been done correctly</p> <p>6 in terms of procedure and inclusion. What do you</p> <p>7 think? We may even ask advice from F Haab who is a</p> <p>8 great support?"</p> <p>9 Did I read that correctly?</p> <p>10 MR. SNELL: Object and leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Is it ever okay for a company to go and</p> <p>15 actually review what types of patients or who --</p> <p>16 strike that.</p> <p>17 Is it ever appropriate for a company</p> <p>18 like Ethicon to go and review the raw data to</p> <p>19 determine whether or not the publication was</p> <p>20 appropriately including the appropriate candidates?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Strike that. Let me ask you a better</p> <p>24 question.</p>

Bruce Alan Rosenzweig, M.D.

Page 318	Page 320
<p>1 Are there ways to manipulate scientific</p> <p>2 data?</p> <p>3 A. Yes.</p> <p>4 Q. What are some of those ways?</p> <p>5 MR. SNELL: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Fail to include patients that have an</p> <p>8 outcome that is not favorable to the conclusions</p> <p>9 that you are looking to draw.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Is it appropriate for medical device</p> <p>12 companies like Ethicon to interfere with the</p> <p>13 publication of safety data?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Why not?</p> <p>19 A. Because that data is important for</p> <p>20 doctors to know so they can have the full view of</p> <p>21 what the experience is with scientists and other</p> <p>22 doctors so they can make an informed decision about</p> <p>23 using a product.</p> <p>24 Q. And does the interference of medical</p>	<p>1 manager, regarding the incontinence platform,</p> <p>2 worldwide marketing team update, August 19, 2007,</p> <p>3 if I believe.</p> <p>4 Q. And what -- what, if anything -- what,</p> <p>5 if anything, did you rely on from this exhibit to</p> <p>6 support your opinions?</p> <p>7 A. This document supports my opinions</p> <p>8 regarding the defects associated with the TVT-Secur</p> <p>9 that were leading to complications. It also</p> <p>10 supports the -- my opinions that the Instructions</p> <p>11 for Use was defective and that even a cookbook</p> <p>12 could not help with the defects of the Instructions</p> <p>13 for Use, that the training associated with the</p> <p>14 TVT-Secur device was not adequate and there was no</p> <p>15 clinical data at the time of launch of the</p> <p>16 TVT-Secur product.</p> <p>17 Q. Can you walk us through Exhibit P0784</p> <p>18 and identify what parts of this exhibit support</p> <p>19 your opinions and describe for the ladies and</p> <p>20 gentlemen of the jury what significance, if any,</p> <p>21 this document has for those opinions?</p> <p>22 A. On TVT-Secur year-to-date findings. It</p> <p>23 would be the I think about the 10th or so page in.</p> <p>24 "Main Difficulties and Complications.</p>
Page 319	Page 321
<p>1 device companies like Ethicon and Johnson & Johnson</p> <p>2 with respect to scientific publications impact the</p> <p>3 knowledge of physicians in a negative way</p> <p>4 concerning products that they may choose to implant</p> <p>5 in their patients?</p> <p>6 MR. SNELL: Objection and leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And how so?</p> <p>11 MR. SNELL: Same.</p> <p>12 BY THE WITNESS:</p> <p>13 A. If information is not being -- accurate</p> <p>14 information is not being put in the literature,</p> <p>15 doctors cannot have knowledge of that information</p> <p>16 in order to be able to share it with patients in</p> <p>17 order to determine what is the best therapy for the</p> <p>18 patient.</p> <p>19 Q. Is there anything else relevant with</p> <p>20 respect to Exhibit 1100 that you want to discuss?</p> <p>21 A. No.</p> <p>22 Q. What's the next document?</p> <p>23 A. It's an internal Ethicon document. It</p> <p>24 is a presentation from Harel Gadot, marketing</p>	<p>1 Insertion difficulties, releasing difficulties,</p> <p>2 fixation tips not staying in place."</p> <p>3 One of the defects that I described is</p> <p>4 that the fleece tips did not -- did not hold the</p> <p>5 device in place so the device -- the stiff, rigid</p> <p>6 mesh would migrate and move which would increase</p> <p>7 the failure rate and also increase the</p> <p>8 complications associated with the device.</p> <p>9 "Bladder perforation, excessive bleeding</p> <p>10 and failures in tensioning," which is a defect in</p> <p>11 the Instructions for Use, trying to describe for</p> <p>12 physicians how to tension.</p> <p>13 On the next page, under No. 7, "Not</p> <p>14 well-defined cookbook procedures" -- "cookbook</p> <p>15 procedure leads to differences in technique between</p> <p>16 surgeons. The learning curve is longer than</p> <p>17 expected. There's a lack of the right training.</p> <p>18 Lack of well-known Key Opinion Leaders advocating</p> <p>19 for the Secur and lack of clinical data."</p> <p>20 Q. Let me just talk about No. 10 really</p> <p>21 quick.</p> <p>22 We had briefly discussed Professor</p> <p>23 Nilsson and Professor Artibani. Do you recall</p> <p>24 that?</p>

Bruce Alan Rosenzweig, M.D.

Page 322	Page 324
<p>1 A. Yes.</p> <p>2 Q. And do you know whether or not</p> <p>3 Dr. Nilsson or Dr. Artibani had any involvement in</p> <p>4 the First Human Use Study?</p> <p>5 A. If I recall, at least Dr. Nilsson was</p> <p>6 part of the First Human Use Study.</p> <p>7 Q. Okay. And by the date or drafting of</p> <p>8 this exhibit of August 19, 2007, what does the</p> <p>9 statement number in No. 10 reflect with respect to</p> <p>10 Dr. Nilsson and Dr. Artibani?</p> <p>11 A. They are not support --</p> <p>12 MR. SNELL: Object. Go ahead.</p> <p>13 BY THE WITNESS:</p> <p>14 A. They are not supporting the TVT-Secur.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And we talked earlier about Dr. Nilsson</p> <p>17 and Dr. Artibani and their concerns with Ethicon</p> <p>18 launching the TVT-Secur product without conducting</p> <p>19 randomized controlled trials.</p> <p>20 Do you recall that?</p> <p>21 A. Yes.</p> <p>22 MR. SNELL: Object and leading.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Okay. And let me ask you this question:</p>	<p>1 document, slide 15.</p> <p>2 MR. THORNBURGH: No, he wants to go here.</p> <p>3 MR. BODYZIAK: This is page 20 of the</p> <p>4 document. Is that the correct one?</p> <p>5 MR. THORNBURGH: For the record it's page 20</p> <p>6 of the document.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And how does page 20 of Exhibit 784</p> <p>9 support your opinions, if at all?</p> <p>10 A. It shows the learning curve, that it</p> <p>11 takes a significant number of procedures to, at</p> <p>12 least at six weeks of follow-up, which is an</p> <p>13 exceedingly short follow-up, get an adequate</p> <p>14 efficacy from the product.</p> <p>15 Q. Okay. So, let's break this down for a</p> <p>16 little bit.</p> <p>17 Dr. Artibani discusses the success rate</p> <p>18 of the first 25 patients.</p> <p>19 Do you see that?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Dr. Lucente.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Dr. Lucente. Strike that.</p>
Page 323	Page 325
<p>1 Do you have an opinion whether or not Dr. Nilsson</p> <p>2 and Dr. Artibani were correct in their concern</p> <p>3 about releasing the TVT-Secur on the market without</p> <p>4 first conducting the appropriate randomized</p> <p>5 controlled trials?</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. They were correct.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And do you -- is there anything else</p> <p>11 with respect to this page of the slide that's</p> <p>12 relevant to your opinions?</p> <p>13 A. That other Key Opinion Leaders are</p> <p>14 insisting on clinical data first.</p> <p>15 Q. Okay. Can you direct us to the next</p> <p>16 part of this exhibit that you rely on would support</p> <p>17 your opinions?</p> <p>18 A. Yes. The "TVT-Secur, Lucente experience</p> <p>19 at 6 weeks follow-up."</p> <p>20 MR. THORNBURGH: And let's go ahead and turn</p> <p>21 there, Tom.</p> <p>22 Tom, what page is that shown for the</p> <p>23 record? What page are we on?</p> <p>24 MR. BODYZIAK: This is page 16 of the</p>	<p>1 So, on page 20 is Dr. Lucente discussing</p> <p>2 his experience at six weeks follow-up?</p> <p>3 A. Correct.</p> <p>4 Q. And in the first 25 patients what were</p> <p>5 Dr. Lucente's results?</p> <p>6 A. The failure rate was 40%.</p> <p>7 Q. And is that an appropriate failure rate?</p> <p>8 A. No, it is not.</p> <p>9 Q. Now, Dr. Artibani then has the "First 77</p> <p>10 Patients," and he writes that there were --</p> <p>11 MR. SNELL: You got to reread do it. You keep</p> <p>12 saying Artibani.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Dr. Lucente then has the results for his</p> <p>15 first 77 patients.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And what does Dr. Lucente report?</p> <p>19 A. A 31% failure rate.</p> <p>20 Q. And what does Dr. Lucente report for all</p> <p>21 136 patients with respect to failure rate?</p> <p>22 A. A 23% failure rate.</p> <p>23 Q. Now, did Dr. Lucente actually continue</p> <p>24 to look at his patients and follow his patients?</p>

82 (Pages 322 to 325)

Bruce Alan Rosenzweig, M.D.

Page 326	Page 328
<p>1 A. Yes.</p> <p>2 Q. And did you review and rely on</p> <p>3 Dr. Lucente's other data concerning his patients?</p> <p>4 A. Yes.</p> <p>5 Q. And who is Dr. Lucente?</p> <p>6 A. Dr. Lucente is a well-known</p> <p>7 urogynecological surgeon, Key Opinion Leader for</p> <p>8 Ethicon.</p> <p>9 Q. And did Dr. Lucente have any involvement</p> <p>10 in the First Human Use Study?</p> <p>11 A. Yes.</p> <p>12 Q. What involvement, if any, did</p> <p>13 Dr. Lucente have there?</p> <p>14 A. He was one of the surgeons that was</p> <p>15 involved in the First Human Use Study.</p> <p>16 Q. Okay. And what's the next document you</p> <p>17 want to discuss?</p> <p>18 A. The next page, the "TVT-Secur take-home</p> <p>19 message."</p> <p>20 MR. THORNBURGH: Hold on one second,</p> <p>21 Dr. Rosenzweig.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. I want to just go back a little bit to</p> <p>24 page 20 of this exhibit, Exhibit 784, and talk to</p>	<p>1 rely on this document?</p> <p>2 A. Yes.</p> <p>3 Q. And what is this document?</p> <p>4 A. It is an e-mail from Stephanie Molden,</p> <p>5 which is a -- she is a partner of Dr. Lucente, and</p> <p>6 it's regarding the TVT-Secur, their TVT-Secur data.</p> <p>7 Q. And you say she was a partner with</p> <p>8 Dr. Lucente. Like Dr. Lucente, do you know whether</p> <p>9 or not she is a urogynecologist?</p> <p>10 A. Yes.</p> <p>11 Q. And does this exhibit, an e-mail</p> <p>12 concerning Dr. Lucente, support any of your</p> <p>13 opinions?</p> <p>14 A. Yes.</p> <p>15 Q. What opinions does it support?</p> <p>16 A. That the design characteristics of the</p> <p>17 TVT-Secur device makes it unreasonably ineffective.</p> <p>18 Q. Okay. And if we look at -- what section</p> <p>19 of this e-mail specifically supports those</p> <p>20 opinions?</p> <p>21 A. The bottom half of the e-mail string is</p> <p>22 a representation of Dr. Lucente's data. We saw in</p> <p>23 the previous slide that at six weeks he was</p> <p>24 reporting a 22% failure rate. Here he has a 14%</p>
Page 327	Page 329
<p>1 you some more about Dr. Lucente.</p> <p>2 And I'll represent to you that the --</p> <p>3 that the metadata on Exhibit 784 shows that it was</p> <p>4 created August 19 of 2007.</p> <p>5 A. Okay.</p> <p>6 Q. Okay. Did you also -- go ahead and mark</p> <p>7 actually as Exhibit P1437, and I think you may have</p> <p>8 it in your binder.</p> <p>9 A. I would not know where it is.</p> <p>10 MR. THORNBURGH: Here. Let me just hand</p> <p>11 you -- go ahead and pull up 1437.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Okay. I found it.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Okay. And so we're looking at -- what</p> <p>16 is it?</p> <p>17 A. P1437.</p> <p>18 Q. And that's in your binder?</p> <p>19 A. Yes.</p> <p>20 Q. Exhibit 5. Yes. And the tab number is</p> <p>21 32?</p> <p>22 A. 31.</p> <p>23 Q. 31. Okay. If we look at Exhibit P1437,</p> <p>24 and let me just ask you quickly, did you review and</p>	<p>1 failure rate at six weeks.</p> <p>2 However, when they look at their</p> <p>3 patients out to one year, their failure rate is</p> <p>4 over 60%.</p> <p>5 Q. Now, what does Stephanie Molden write</p> <p>6 with respect to these results?</p> <p>7 A. "I'm not really looking too much at one</p> <p>8 year patients since we know they are worse. But</p> <p>9 excluding those, our rates are steadily decreasing</p> <p>10 with longer follow-up in a cohort of 247 patients."</p> <p>11 Q. And she goes on to say, "Not sure why</p> <p>12 the 3 to 4 month rate is lower than the 6 months,</p> <p>13 but Secur appears not to hold up with time."</p> <p>14 Did I read that correctly?</p> <p>15 A. Yes.</p> <p>16 Q. Does that support any of your opinions?</p> <p>17 MR. SNELL: Object; leading.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What about this -- this statement from</p> <p>22 Ms. Molden support your opinions and what opinions</p> <p>23 specifically does it support?</p> <p>24 A. It supports my opinions that there are</p>

83 (Pages 326 to 329)

Bruce Alan Rosenzweig, M.D.

Page 330	Page 332
<p>1 characteristics of the device that make it</p> <p>2 unreasonably ineffective to treat stress urinary</p> <p>3 incontinence.</p> <p>4 Q. Now, Dr. Molden says that when they</p> <p>5 exclude the one year -- strike that.</p> <p>6 Dr. Molden states that "I'm not really</p> <p>7 looking too much at the one year patients since we</p> <p>8 know they were worse."</p> <p>9 Do you have any understanding as to why</p> <p>10 they knew the one-year patients would be worse?</p> <p>11 MR. SNELL: Objection and leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, since this is from January of</p> <p>14 2008, those patients were done before January of</p> <p>15 2007.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Would that -- first -- would those be</p> <p>18 the earlier patients?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Potentially.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Would those patients potentially be part</p> <p>24 of the learning curve?</p>	<p>1 Q. Are those good results, Doctor?</p> <p>2 A. No.</p> <p>3 Q. By -- by the -- that three-to-four month</p> <p>4 period, do you have an understanding of whether or</p> <p>5 not Dr. Lucente would have overcome the learning</p> <p>6 curve?</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And what's that opinion?</p> <p>12 A. He would have overcome the learning</p> <p>13 curve.</p> <p>14 Q. Did the learning curve have any impact</p> <p>15 on the -- strike that.</p> <p>16 Does that -- does that fact or issue</p> <p>17 support any of your opinions and, if so, what</p> <p>18 opinions?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That the TVT-Secur is not effective in</p> <p>22 treating stress urinary incontinence. There are</p> <p>23 design characteristics that make it unreasonably</p> <p>24 ineffective in treating stress urinary</p>
Page 331	Page 333
<p>1 A. Potentially.</p> <p>2 Q. And if Dr. Molden is -- she says, even</p> <p>3 if we exclude those first patients from the</p> <p>4 one-year data, did that have any impact on the</p> <p>5 success over time of the TVT-Secur product?</p> <p>6 MR. SNELL: Object and leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No, because the success does not hold up</p> <p>9 with time.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. So, if we look at the data, you'll see</p> <p>12 that at one year at January 18, 2008, what was the</p> <p>13 failure rate?</p> <p>14 A. Over 60%.</p> <p>15 Q. Are those good results?</p> <p>16 A. No.</p> <p>17 Q. And if you look at the six-month data,</p> <p>18 what was the failure rate?</p> <p>19 A. Over 25%.</p> <p>20 Q. If you look at the three-to-four-month</p> <p>21 data, what was the success rate?</p> <p>22 A. The --</p> <p>23 Q. The failure rate. I'm sorry.</p> <p>24 A. Over 33%.</p>	<p>1 incontinence.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Okay.</p> <p>4 MR. SNELL: While they are conferring I will</p> <p>5 put an objection. P1437 not on reliance list.</p> <p>6 MR. THORNBURGH: Yes, it is.</p> <p>7 MR. SNELL: I know it's on the one you just</p> <p>8 served, but it wasn't on the one that led to him</p> <p>9 drafting and formulating his opinions, putting them</p> <p>10 to paper, et cetera. So, that's all. I'm not</p> <p>11 trying to argue with you.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Now, let's go back to P1437 really</p> <p>14 quick. What is Vincent Lucente's response?</p> <p>15 MR. SNELL: Object; reading.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Is there anything relevant or</p> <p>18 significant to Dr. Lucente's response that you'd</p> <p>19 like to discuss with the jury?</p> <p>20 If we just orient ourselves really</p> <p>21 quick, did Dr. Lucente respond to the data that was</p> <p>22 forwarded by his partner Dr. Molden?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>

84 (Pages 330 to 333)

Bruce Alan Rosenzweig, M.D.

Page 334	Page 336
<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And what does Dr. Lucente indicate with</p> <p>4 respect to his concern about the TVT-Secur efficacy</p> <p>5 when compared to Ethicon's other TVT Retropubic and</p> <p>6 TVT-O devices?</p> <p>7 MR. SNELL: Objection; leading.</p> <p>8 BY THE WITNESS:</p> <p>9 A. He states that "It may be our 'hard</p> <p>10 line' definition of 'dry' versus 'success.' As you</p> <p>11 know for SUI in Hilton-Ward randomized controlled</p> <p>12 trial Burch v TVT, the TVT success rate was 58%."</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And then he says -- what's the next</p> <p>15 sentence after that?</p> <p>16 MR. SNELL: Same.</p> <p>17 BY THE WITNESS:</p> <p>18 A. "Nonetheless, very concerning when</p> <p>19 compared to our TVT and TVT-O long-term dryness</p> <p>20 rates."</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And what is the significance, if</p> <p>23 anything, with respect to Dr. Lucente's response?</p> <p>24 MR. SNELL: Object.</p>	<p>1 A. I do recall an abstract from Stephanie</p> <p>2 Molden.</p> <p>3 MR. THORNBURGH: Just give me one second.</p> <p>4 Can we go off the record real quick.</p> <p>5 THE VIDEOGRAPHER: The time is 5:18 p.m. and</p> <p>6 we are going off the video record.</p> <p>7 (WHEREUPON, a recess was had</p> <p>8 from 5:18 to 5:26 p.m.)</p> <p>9 THE VIDEOGRAPHER: The time is 5:26 p.m. and</p> <p>10 we're back on the video record.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Okay. Dr. Rosenzweig, before we went</p> <p>13 off the record to break, we were looking at two</p> <p>14 exhibits, one was P1437, which was the e-mail that</p> <p>15 contained Dr. Lucente's data and dated January 21</p> <p>16 of 2008, and the other exhibit that we had looked</p> <p>17 at was Exhibit P784, which had just the six-week</p> <p>18 data from Dr. Lucente's experience with the</p> <p>19 TVT-Secur.</p> <p>20 Do you recall that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Now, if we look at 1437, you'll</p> <p>23 see that after Stephanie Molden circulates their</p> <p>24 one-year data, that there's a discussion by</p>
Page 335	Page 337
<p>1 BY THE WITNESS:</p> <p>2 A. It shows that the TVT-Secur has a lower</p> <p>3 success rate than TVT and TVT-O.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Now, Dr. Ciarrocca responds. Do you see</p> <p>6 that?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I don't know if Scott Ciarrocca is a</p> <p>10 doctor.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. I'm sorry. Mr. Ciarrocca. Scott</p> <p>13 Ciarrocca. Is he an Ethicon employee?</p> <p>14 A. Yes.</p> <p>15 Q. And what does Mr. Ciarrocca respond?</p> <p>16 A. "I think we need to probe this data with</p> <p>17 him."</p> <p>18 Q. Did Dr. Lucente end up publishing his</p> <p>19 data, his one-year data?</p> <p>20 A. Not that I specifically recall.</p> <p>21 Q. Do you know whether or not there is any</p> <p>22 abstracts from Dr. Molden or Dr. Lucente</p> <p>23 concerning -- not published in a peer-reviewed</p> <p>24 setting but any abstracts that were presented?</p>	<p>1 Dr. Lucente about the data concerning when compared</p> <p>2 to the TVT and TVT-O data and then if you look at</p> <p>3 the very top of this exhibit, Scott Ciarrocca of</p> <p>4 Ethicon says, "Guys, I think we need to probe this</p> <p>5 data with him."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And then I gave you</p> <p>9 Exhibit P2225. Had you seen Exhibit P2225 before?</p> <p>10 MR. SNELL: I'm going to object. It's not on</p> <p>11 his reliance list as far as we can tell.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Do you recall being questioned about it</p> <p>14 at the last trial?</p> <p>15 A. I do recall that, yes.</p> <p>16 Q. Do you recall William Gage</p> <p>17 cross-examined you at length concerning P2225?</p> <p>18 A. I do recall that, yes.</p> <p>19 Q. Okay. And what does -- what does -- and</p> <p>20 is P2225 the one-year outcome abstract, published</p> <p>21 abstract concerning Dr. Lucente and Molden's</p> <p>22 one-year data?</p> <p>23 MR. SNELL: Object to the document still and</p> <p>24 leading now. Go ahead.</p>

Bruce Alan Rosenzweig, M.D.

Page 338	Page 340
<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What is Exhibit P2225?</p> <p>5 A. It is an abstract regarding the one-year</p> <p>6 outcome data for TVT-Secur.</p> <p>7 Q. And if you turn to the last page of</p> <p>8 Exhibit P2225, you'll see there is a date that</p> <p>9 says, "Here is updated Secur data as of April 8,</p> <p>10 2008." Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Now, Scott Ciarrocca writes to</p> <p>13 his colleagues within Ethicon in P1437 and says,</p> <p>14 "I think we need to probe this data with him," on</p> <p>15 January 21, 2008. Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And what ultimately gets reported</p> <p>18 as the one-year data a few months later in P2225</p> <p>19 concerning the one-year data that's discussed</p> <p>20 initially in P1437?</p> <p>21 MR. SNELL: Objection. Go ahead.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Side by side, but go to page 1.</p> <p>24 If you just look at -- if you look at --</p>	<p>1 Q. Are there any differences in the data?</p> <p>2 A. Yes.</p> <p>3 MR. SNELL: Same.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What are the differences?</p> <p>6 A. The dryness rate that is reported in the</p> <p>7 abstract is close -- is approximately 70% where it</p> <p>8 is less than 40% in the internal e-mail.</p> <p>9 Q. Does that -- those -- does this have any</p> <p>10 significance or importance with respect to your</p> <p>11 opinions?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. We see that Scott Ciarrocca states that</p> <p>15 "We will need to probe this data with him," and we</p> <p>16 see differences even on the last page of this</p> <p>17 document where they -- Stephanie Molden's name is</p> <p>18 below that -- their one-year completely dry rate is</p> <p>19 reported here as 51%, here it's 70%, and in the</p> <p>20 e-mail it's 40%.</p> <p>21 Q. Is it --</p> <p>22 A. So, there are a variety of different</p> <p>23 numbers at the same time frame for the one-year</p> <p>24 dryness rate.</p>
Page 339	Page 341
<p>1 I'm trying to streamline this because I know</p> <p>2 opposing counsel has to leave.</p> <p>3 If you go to under the "Results"</p> <p>4 section, beginning with, "There was significant</p> <p>5 decrease in dryness."</p> <p>6 A. Yes.</p> <p>7 MR. THORNBURGH: Go ahead and blow that up,</p> <p>8 Tom.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And highlight beginning with midway</p> <p>11 through where it says, "There was significant</p> <p>12 decrease in dryness rate from two weeks 91.3% to</p> <p>13 one year postoperatively 69%."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 MR. SNELL: Object; leading.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. So, behind closed doors -- strike that.</p> <p>19 Do you see any differences between what</p> <p>20 was being discussed internally in Ethicon's e-mails</p> <p>21 with Dr. Lucente versus what ultimately got</p> <p>22 published?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 Q. Doctor, I didn't create these exhibits,</p> <p>2 did I?</p> <p>3 A. No.</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Whose exhibits do they belong to? Whose</p> <p>7 documents do these belong to?</p> <p>8 A. These are internal Ethicon documents.</p> <p>9 Q. Doctor, is it ever appropriate --</p> <p>10 MR. SNELL: Objection; misstates the evidence.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Is it ever appropriate for a medical</p> <p>13 device company who receives concerning information</p> <p>14 about the efficacy of its medical devices to</p> <p>15 intervene with the researchers of the data and get</p> <p>16 that data changed?</p> <p>17 MR. SNELL: Objection and misstates the</p> <p>18 evidence.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Why not?</p> <p>23 A. Because doctors should be given complete</p> <p>24 and accurate information regarding the efficacy and</p>

86 (Pages 338 to 341)

Bruce Alan Rosenzweig, M.D.

Page 342	Page 344
<p>1 complications associated with the medical device.</p> <p>2 Q. If the one-year data showed a failure</p> <p>3 rate of greater than 60%, should Ethicon have</p> <p>4 described or should these -- strike that.</p> <p>5 If the -- if the accurate information at</p> <p>6 one year for Dr. Molden and Lucente's data was a</p> <p>7 failure rate of or success rate of only 38.5%, is</p> <p>8 that the data that should have been disclosed to</p> <p>9 physicians?</p> <p>10 MR. SNELL: Objection and misstates the</p> <p>11 evidence.</p> <p>12 BY THE WITNESS:</p> <p>13 A. That would have been important data to</p> <p>14 disclose to physicians.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And by disclosing data that shows a</p> <p>17 higher efficacy rate, does that or does that --</p> <p>18 does that in any way impact potentially the</p> <p>19 risk/benefit assessment that physicians perform</p> <p>20 when deciding which treatment options to recommend</p> <p>21 to their patients?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. It would be difficult for a doctor to</p>	<p>1 Is there anything significant with that</p> <p>2 fact to your opinions?</p> <p>3 MR. SNELL: Object.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Well, in the e-mail they're talking</p> <p>6 about 247 patients. In this document from</p> <p>7 Stephanie Molden the N is 267 patients. And in the</p> <p>8 abstract, which seems to have included another</p> <p>9 physician beside Dr. Lucente's data, Dr. Olson,</p> <p>10 because you see that this is data collected at two</p> <p>11 different hospitals, the total number of patients</p> <p>12 that underwent the Secur were 349 patients but only</p> <p>13 149 were evaluated at one year.</p> <p>14 So, it's really difficult to say the</p> <p>15 exact data set that they're looking at, but there</p> <p>16 are differences in the numbers that are reported.</p> <p>17 Q. And are there ways to pull data that</p> <p>18 could provide inaccurate information?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Correct.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. In other words, if you -- if you knew</p> <p>24 that your results were poor and you had a 30 --</p>
Page 343	Page 345
<p>1 accurately give a risk/benefit analysis to their</p> <p>2 patient if they're not provided with accurate</p> <p>3 information regarding the risks and benefits</p> <p>4 associated with a medical device.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Now, did Dr. -- based on the exhibits</p> <p>7 that we just looked at, P2225, P1437, and P1437,</p> <p>8 did Dr. Molden and Dr. Lucente's data get better or</p> <p>9 worse after Mr. Ciarrocca of Ethicon said that they</p> <p>10 needed to probe Dr. Lucente's data with him?</p> <p>11 MR. SNELL: Object.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Looking at the numbers, there is a</p> <p>14 change in the dryness rate from 38.5% that is in</p> <p>15 one document to 51% in another document to 69% in</p> <p>16 another document.</p> <p>17 Q. Does that suggest anything to you?</p> <p>18 MR. SNELL: Objection.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Let me ask a better question.</p> <p>21 Do you have an opinion whether or not</p> <p>22 this evidence suggests anything -- is there</p> <p>23 anything significant about that issue -- strike</p> <p>24 that.</p>	<p>1 only a 38% success rate, could you add some other</p> <p>2 doctors' patients to your pool who had a better</p> <p>3 success rate to increase your numbers, to make your</p> <p>4 numbers look better?</p> <p>5 MR. SNELL: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Possibly.</p> <p>8 MR. THORNBURGH: I think -- did you guys want</p> <p>9 to break now?</p> <p>10 MR. SNELL: Yes, it's 5:40.</p> <p>11 BY THE WITNESS:</p> <p>12 A. There is one last thing that we wanted</p> <p>13 to talk about on this.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. I'm sorry. You're right.</p> <p>16 MR. THORNBURGH: Go back on the record.</p> <p>17 THE VIDEOGRAPHER: I didn't go off.</p> <p>18 BY THE WITNESS:</p> <p>19 A. And it's the take-home message from</p> <p>20 TVT-Secur.</p> <p>21 MR. SNELL: Are you on this part, Doctor?</p> <p>22 THE WITNESS: Yes, the next -- the next page.</p> <p>23 BY THE WITNESS:</p> <p>24 A. And just to complete this one exhibit,</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 346</p> <p>1 the take-home message from TVT-Secur, "It is</p> <p>2 completely different from TVT and TVT-O." The --</p> <p>3 you have to "live through the learning curve of 20</p> <p>4 cases," and the learning curve can be as long as 5</p> <p>5 to 20 weeks.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And why are those -- those issues that</p> <p>8 you identified significant to your opinions?</p> <p>9 A. It is completely different from the TVT</p> <p>10 and TVT-O. Therefore, you cannot use the TVT and</p> <p>11 TVT-O data to state that the TVT-Secur will have</p> <p>12 the same data because it is a completely different</p> <p>13 product and the length of the learning curve shows</p> <p>14 that there is a defect in the Instructions for Use.</p> <p>15 Q. Any other significant information from</p> <p>16 Exhibit 784 that you want to discuss?</p> <p>17 A. No.</p> <p>18 MR. THORNBURGH: I think that concludes the</p> <p>19 day.</p> <p>20 MR. SNELL: All right.</p> <p>21 MR. THORNBURGH: Thank you, Doctor.</p> <p>22 THE VIDEOGRAPHER: Okay. Shall I go off the</p> <p>23 record?</p> <p>24 MR. THORNBURGH: Sure.</p>	<p style="text-align: right;">Page 348</p> <p>1 I, CORINNE T. MARUT, C.S.R. No. 84-1968,</p> <p>2 Registered Professional Reporter and Certified</p> <p>3 Shorthand Reporter, do hereby certify:</p> <p>4 That previous to the commencement of the</p> <p>5 examination of the witness, the witness was duly</p> <p>6 sworn to testify the whole truth concerning the</p> <p>7 matters herein;</p> <p>8 That the foregoing deposition transcript</p> <p>9 was reported stenographically by me, was thereafter</p> <p>10 reduced to typewriting under my personal direction</p> <p>11 and constitutes a true record of the testimony</p> <p>12 given and the proceedings had;</p> <p>13 That the said deposition was taken</p> <p>14 before me at the time and place specified;</p> <p>15 That the reading and signing by the</p> <p>16 witness of the deposition transcript was agreed</p> <p>17 upon as stated herein;</p> <p>18 That I am not a relative or employee or</p> <p>19 attorney or counsel, nor a relative or employee of</p> <p>20 such attorney or counsel for any of the parties</p> <p>21 hereto, nor interested directly or indirectly in</p> <p>22 the outcome of this action.</p> <p>23 It was requested before completion of</p> <p>24 the deposition that the witness, BRUCE ALAN</p> <p>ROSENZWEIG, M.D., have the opportunity to read and</p> <p>sign the deposition transcript.</p> <p style="text-align: center;">CORINNE T. MARUT, Certified Reporter</p> <p>(The foregoing certification of this</p> <p>transcript does not apply to any</p> <p>reproduction of the same by any means, unless under</p> <p>the direct control and/or supervision of the</p> <p>certifying reporter.)</p>
<p style="text-align: right;">Page 347</p> <p>1 THE VIDEOGRAPHER: Okay. The time is 5:39</p> <p>2 p.m. and we're going off the video record.</p> <p>3 (WHEREUPON, at 5:39 p.m. the</p> <p>4 videotaped de bene esse deposition</p> <p>5 of BRUCE ALAN ROSENZWEIG, M.D. was</p> <p>6 adjourned, to be reconvened at 9:00</p> <p>7 a.m., on Saturday, July 15, 2017.)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 349</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections. You</p> <p>5 should state the reason in the appropriate space on</p> <p>6 the errata sheet for any corrections that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet, which</p> <p>11 will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the</p> <p>15 deposition transcript by you. If you fail to do</p> <p>16 so, the deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>